AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

FEDERAL REGISTER

Vol. 88 Monday,
No. 145 July 31, 2023

Pages 49267–49992

OFFICE OF THE FEDERAL REGISTER

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

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

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

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

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

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

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

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

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

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

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–09512—1800**
Assistance with public subscriptions	**202–512–1806**

General online information **202–512–1530; 1–888–293–6498**

Single copies/back copies:

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

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

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

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

Printed on recycled paper.

Contents

Federal Register

Vol. 88, No. 145

Monday, July 31, 2023

Agricultural Marketing Service
PROPOSED RULES
Adjustments to Mango Board Representation, 49356–49357

Agriculture Department
See Agricultural Marketing Service
See Forest Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49434

Centers for Disease Control and Prevention
NOTICES
Meetings:
Board of Scientific Counselors, National Center for Health Statistics, 49463
Board of Scientific Counselors, National Center for Injury Prevention and Control, 49463–49464
National Center for Health Statistics, ICD–10 Coordination and Maintenance Committee, 49465–49466
Requests for Nominations:
Appointment to Advisory Committee to the Director Data and Surveillance Workgroup, 49464–49465

Centers for Medicare & Medicaid Services
RULES
Medicare Program:
Alternative Payment Model Incentive Payment Advisory for Clinicians, Request for Current Billing Information for Qualifying Participants, 49309
PROPOSED RULES
Medicare Program:
Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc., 49552–49921
NOTICES
Meetings:
Ground Ambulance and Patient Billing Advisory Committee, 49466–49467

Civil Rights Commission
NOTICES
Meetings:
Guam Advisory Committee, 49436
Northern Mariana Islands Advisory Committee, 49436

Coast Guard
RULES
Drawbridge Operations:
Atlantic Intracoastal Waterway; West Palm Beach, FL, 49287–49288
Safety Zone:
Fleet Week Maritime Festival, Pier 62, Elliot Bay, Seattle, WA, 49288–49290
Lake Erie, Cleveland, OH, 49290–49292
Mercury Powerboat Race; Sheboygan Harbor, Sheboygan, WI, 49292–49294

Commerce Department
See Foreign-Trade Zones Board
See International Trade Administration
See National Institute of Standards and Technology
See National Oceanic and Atmospheric Administration

Copyright Office, Library of Congress
RULES
Copyright Claims Board:
District Court Referrals; Proof of Service Forms; Default Proceedings; Law Student Representation, 49294–49295

Corporation for National and Community Service
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application Instructions for AmeriCorps State and National Competitive, New, and Continuation Grants, 49452–49453
Application Package for AmeriCorps Application Questions, 49453–49454

Council on Environmental Quality
PROPOSED RULES
National Environmental Policy Act Implementing Regulations Revisions Phase 2, 49924–49988

Defense Department
NOTICES
Meetings:
Defense Business Board, 49454–49455
Defense Science Board, 49455

Education Department
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application for the Fulbright-Hays Group Projects Abroad Program, 49455–49456
Program for International Student Assessment 2025 Main Study Recruitment and Field Test, 49457–49458
Regional Educational Laboratories Pacific Efficacy and Implementation Evaluation of the Secondary Writing Toolkit, 49456–49457

Employee Benefits Security Administration
NOTICES
Exemption from Certain Prohibited Transaction Restrictions:
J.P. Morgan Securities LLC, J.P. Morgan Investment Management Inc., J.P. Morgan Advisors (formerly, J.P. Morgan Securities; JPMS Brokerage), and Chase Wealth Management, 49497–49502

Employment and Training Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
O*NET Data Collection Program, 49502–49503

Energy Department
See Western Area Power Administration

Environmental Protection Agency
RULES
Federal Good Neighbor Plan for the 2015 Ozone National Ambient Air Quality Standards; Response to Judicial Stays of State Implementation Plan Disapproval Action for Certain States, 49295–49309
PROPOSED RULES
Air Quality State Implementation Plans; Approvals and Promulgations:
Washington; Southwest Clean Air Agency, General Air Quality Regulations, 49398–49402
National Emission Standards for Hazardous Air Pollutants:
Integrated Iron and Steel Manufacturing Facilities Technology Review, 49402–49423
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Indoor airPLUS Program, 49459–49460
On-Highway Motorcycle Certification and Compliance Program, 49460–49461
Air Pollution Control:
Proposed Administrative Action on Clean Air Act Grant to the Puerto Rico Department of Natural and Environmental Resources, 49461–49462

Farm Credit Administration
NOTICES
Meetings; Sunshine Act, 49462

Federal Aviation Administration
RULES
Airworthiness Directives:
Airbus SAS Airplanes, 49275–49277
Embraer S.A. (Type Certificate Previously Held by Yabora Industria Aeronautica S.A.; Embraer S.A.) Airplanes, 49277–49280
Fokker Services B.V. Airplanes, 49280–49283
The Boeing Company Airplanes, 49284–49287
PROPOSED RULES
Airworthiness Directives:
Rolls-Royce Deutschland Ltd and Co KG Engines, 49361–49364

Federal Communications Commission
PROPOSED RULES
Shared Use of the 42–42.5 GHz Band, 49423–49433

Federal Deposit Insurance Corporation
NOTICES
Meetings; Sunshine Act, 49462–49463

Federal Emergency Management Agency
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Revisions to National Flood Insurance Program Maps: Application Forms and Instructions for (C)Letter of Map Amendments and (C)Letter of Map Revision—Based on Fills, 49484–49485
Flood Hazard Determinations, 49479–49487

Federal Trade Commission
PROPOSED RULES
Trade Regulation Rule on the Use of Consumer Reviews and Testimonials, 49364–49392

Fish and Wildlife Service
RULES
General Provisions; Revised List of Migratory Birds, 49310–49355

Food and Drug Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Product Jurisdiction and Combination Products, 49467–49469
State Petitions for Exemption from Preemption, 49469–49471

Foreign-Trade Zones Board
NOTICES
Authorization of Production Activity:
Airbus OneWeb Satellites, North America LLC, Foreign-Trade Zone 136, Merritt Island, FL, 49437

Forest Service
NOTICES
Revision of Land Management Plan:
Blue Mountains Forests, Malheur, Umatilla, and Wallowa-Whitman National Forests, Oregon and Washington, 49434–49436

Health and Human Services Department
See Centers for Disease Control and Prevention
See Centers for Medicare & Medicaid Services
See Food and Drug Administration
See National Institutes of Health
See Substance Abuse and Mental Health Services Administration
PROPOSED RULES
Medicare Program:
Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; etc., 49552–49921

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency
See U.S. Citizenship and Immigration Services
See U.S. Customs and Border Protection

Housing and Urban Development Department
PROPOSED RULES
Modernization of Engagement with Mortgagors in Default, 49392–49397
NOTICES
Funding Opportunity:
Pathways to Removing Obstacles to Housing, 49488–49489

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service
See Reclamation Bureau
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
PROPOSED RULES
Rules for Supervisory Approval of Penalties:
Hearing, 49397

International Trade Administration
NOTICES
Antidumping or Countervailing Duty Investigations, Orders, or Reviews:
Certain Corrosion-Resistant Steel Products from the Republic of Korea, 49440–49442
Certain Steel Nails from the Republic of Korea, 49443–49446
Citric Acid and Certain Citrate Salts from Belgium, 49442–49443
Common Alloy Aluminum Sheet from Germany, 49446–49448
Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled into Modules, from the People's Republic of China, 49448–49450
Monosodium Glutamate from the Republic of Indonesia, 49437–49438
Prestressed Concrete Steel Wire Strand from Mexico, 49438–49440

Justice Department
NOTICES
Proposed Consent Decree, 49496
Proposed Consent Decree:
CERCLA, 49495
Clean Air Act, 49495–49496
Clean Air Act and Emergency Planning and Community Right-to-Know Act, 49496–49497

Labor Department
See Employee Benefits Security Administration
See Employment and Training Administration
See Occupational Safety and Health Administration

Land Management Bureau
NOTICES
Plats of Survey:
New Mexico, Oklahoma, 49489

Library of Congress
See Copyright Office, Library of Congress

National Archives and Records Administration
NOTICES
Records Schedules, 49504–49505

National Institute of Standards and Technology
NOTICES
Meetings:
National Construction Safety Team Advisory Committee, 49450–49451

National Institutes of Health
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49472–49473
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Generic Clearance for Citizen Science and Crowdsourcing Projects, 49473–49474
Meetings:
National Heart, Lung, and Blood Institute, 49471
National Human Genome Research Institute, 49473
National Institute of Arthritis and Musculoskeletal and Skin Diseases, 49471
National Institute of Neurological Disorders and Stroke, 49471–49472

National Oceanic and Atmospheric Administration
NOTICES
Meetings:
Gulf of Mexico Fishery Management Council, 49451
New England Fishery Management Council, 49451–49452

National Park Service
NOTICES
Meetings:
Alaska Region Subsistence Resource Commission Program, 49491–49493
Preservation Technology and Training Board, 49489–49490
National Register of Historic Places:
Pending Nominations and Related Actions, 49490–49491

National Science Foundation
NOTICES
Permits:
Antarctic Conservation Act, 49505–49506

Nuclear Regulatory Commission
RULES
List of Approved Spent Fuel Storage Casks:
NAC International, Inc. MAGNASTOR Storage System, Certificate of Compliance No. 1031, Amendment Nos. 11 and 12 and Revisions to Amendment Nos. 0 through 9, 49267–49275
PROPOSED RULES
List of Approved Spent Fuel Storage Casks:
NAC International, Inc. MAGNASTOR Storage System, Certificate of Compliance No. 1031, Amendment Nos. 11 and 12 and Revisions to Amendment Nos. 0 through 9, 49357–49361

Occupational Safety and Health Administration
NOTICES
Requests for Nominations:
National Advisory Committee on Occupational Safety and Health, 49503–49504

Postal Regulatory Commission
NOTICES
New Postal Products, 49506

Postal Service
NOTICES
Product Change:
Priority Mail and Ground Advantage Negotiated Service Agreement, 49506–49508
Priority Mail Express, Priority Mail, and Ground Advantage Negotiated Service Agreement, 49507
Priority Mail Negotiated Service Agreement, 49507
Priority Mail, First-Class Package Service and Parcel Select Negotiated Service Agreement, 49507

Presidential Documents
PROCLAMATIONS
Special Observances:
National Korean War Veterans Armistice Day (Proc. 10604), 49989–49992

Reclamation Bureau
NOTICES
Meetings:
Glen Canyon Dam Adaptive Management Work Group, 49493

Securities and Exchange Commission
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49512, 49515–49516, 49521–49522
Meetings; Sunshine Act, 49512–49513
Self-Regulatory Organizations; Proposed Rule Changes:
Cboe BYX Exchange, Inc., 49540–49542
Cboe BZX Exchange, Inc., 49518–49521, 49526–49528
Cboe EDGA Exchange, Inc., 49513–49515
Cboe EDGX Exchange, Inc., 49516–49518
ICE Clear Europe Ltd., 49545–49548
Investors Exchange LLC, 49542–49545
Municipal Securities Rulemaking Board, 49528–49540
NYSE Arca, Inc., 49508
The Nasdaq Stock Market LLC, 49508–49512
The Nasdaq Stock Market, LLC, 49522–49526

Small Business Administration
NOTICES
Disaster Declaration:
Colorado, 49548–49549

Substance Abuse and Mental Health Services Administration
NOTICES
Meetings:
Joint Meeting of the National Advisory Councils, 49475
National Advisory Council, 49474–49475

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Restrictions on Financial Interests of State Employees, 49494–49495
Technical Evaluation Surveys, 49493–49494

Surface Transportation Board
NOTICES
Meetings:
National Grain Car Council, 49549

Transportation Department
See Federal Aviation Administration

Treasury Department
See Internal Revenue Service

U.S. Citizenship and Immigration Services
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Petition for Alien Relative, 49487–49488

U.S. Customs and Border Protection
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals:
Application to Pay Off or Discharge Alien Crewman, 49477–49478
Foreign Assembler's Declaration, 49475–49476
General Declaration, 49476–49477
Petroleum Refineries in Foreign Trade Sub-Zones, 49478–49479

Western Area Power Administration
NOTICES
Agency Information Collection Activities; Proposals, Submissions, and Approvals, 49458–49459

Separate Parts In This Issue

Part II
Health and Human Services Department, Centers for Medicare & Medicaid Services, 49552–49921
Health and Human Services Department, 49552–49921

Part III
Council on Environmental Quality, 49924–49988

Part IV
Presidential Documents, 49989–49992

Reader Aids

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

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

CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Proclamations:

10604 49991

7 CFR

Proposed Rules:

1206 49356

10 CFR

72 49267

Proposed Rules:

72 49357

14 CFR

39 (4 documents) 49275, 49277, 49280, 49284

Proposed Rules:

39 49361

16 CFR

Proposed Rules:

465 49364

24 CFR

Proposed Rules:

203 49392

26 CFR

Proposed Rules:

301 49397

33 CFR

117 49287

165 (3 documents) 49288, 49290, 49292

37 CFR

222 49294

224 49294

225 49294

233 49294

234 49294

235 49294

40 CFR

52 49295

97 49295

Proposed Rules:

52 49398

63 49402

1500 49924

1501 49924

1502 49924

1503 49924

1504 49924

1505 49924

1506 49924

1507 49924

1508 49924

42 CFR

414 49309

Proposed Rules:

405 49552

410 49552

416 49552

419 49552

424 49552

485 49552

488 49552

489 49552

45 CFR

Proposed Rules:

180 49552

47 CFR

Proposed Rules:

0 49423

50 CFR

10 49310

17 49310

21 49310

Rules and Regulations

Federal Register

Vol. 88, No. 145

Monday, July 31, 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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2023–0085]

RIN 3150–AK99

List of Approved Spent Fuel Storage Casks: NAC International, Inc. MAGNASTOR® Storage System, Certificate of Compliance No. 1031, Amendment Nos. 11 and 12 and Revisions to Amendment Nos. 0 Through 9

AGENCY: Nuclear Regulatory Commission.

ACTION: Direct final rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is amending its spent fuel storage regulations by revising the NAC International, Inc. MAGNASTOR® Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031. Amendment No. 11 amends the certificate of compliance to add a new concrete cask, transfer cask, fuel baskets and revised contents. Amendment No. 11 also adds a definition for the concrete cask lid, revises the definition for the concrete cask to exclude the lid, adds a definition for the storage cask, and provides alternate fabrication criteria and techniques for the concrete cask lid. Amendment No. 12 and revisions to Amendment Nos. 0 through 9 add definitions for the storage cask and concrete cask lid, revise the definition of the concrete cask, and provide alternate fabrication criteria and techniques for the concrete cask lid to the certificate of compliance.

DATES: This direct final rule is effective October 16, 2023, unless significant adverse comments are received by August 30, 2023. If this direct final rule is withdrawn as a result of such comments, timely notice of the withdrawal will be published in the **Federal Register**. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Comments received on this direct final rule will also be considered to be comments on a companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register**.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2023–0085, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Bernard White, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–6577, email: *Bernard.White@nrc.gov* and Irene Wu, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
IV. Discussion of Changes
V. Voluntary Consensus Standards
VI. Agreement State Compatibility
VII. Plain Writing
VIII. Environmental Assessment and Finding of No Significant Impact
IX. Paperwork Reduction Act Statement
X. Regulatory Flexibility Certification
XI. Regulatory Analysis
XII. Backfitting and Issue Finality
XIII. Congressional Review Act
XIV. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0085 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0085. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2023–0085 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS.

The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

This rule is limited to the changes contained in Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031 and does not include other aspects of the NAC International, Inc. MAGNASTOR® Storage System design. The NRC is using the ''direct final rule procedure'' to issue this amendment because it represents a limited and routine change to an existing certificate of compliance that is expected to be non-controversial. Adequate protection of public health and safety continues to be reasonably assured. The amendments to the rule will become effective on October 16, 2023. However, if the NRC receives any significant adverse comment on this direct final rule by August 30, 2023, then the NRC will publish a document that withdraws this action and will subsequently address the comments received in a final rule as a response to the companion proposed rule published in the Proposed Rules section of this issue of the **Federal Register** or as otherwise appropriate. In general, absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule, certificate of compliance, or technical specifications.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' that contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC International, Inc. MAGNASTOR® Storage System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1031.

IV. Discussion of Changes

On July 14, 2020, NAC International, Inc. submitted a request to the NRC to add Amendment No. 11 to Certificate of Compliance No. 1031. NAC International, Inc. supplemented its request on August 23, 2021, January 11, 2022, March 18, 2022, April 18, 2022, and July 15, 2022. Amendment No. 11 amends the certificate of compliance as follows:

1. Adds a seventh concrete overpack (CC7) and a lightweight MAGNASTOR® transfer cask (LMTC).
2. Increases the maximum heat load for the system when using CC7 and the LMTC.
3. Adds new loading patterns.
4. Adds new 81-assembly and 89-assembly boiling-water reactor (BWR) spent fuel basket designs and associated loading patterns.
5. Removes existing 87-assembly and 82-assembly BWR basket designs.
6. Adds a new BWR damaged fuel basket design with a capacity of up to 81 undamaged BWR fuel assemblies.
7. Adds a new damaged fuel can for BWR fuel.
8. Adds a definition for concrete cask lid.
9. Revises the definition for concrete cask to exclude the lid.
10. Adds a definition for storage cask.
11. Provides alternate fabrication criteria and techniques for the concrete cask lid.

On January 24, 2022, NAC International, Inc. submitted a request to the NRC to add Amendment No. 12 to Certificate of Compliance No. 1031. NAC International, Inc. supplemented its request on March 18, 2022, and April 18, 2022. As part of its request on March 18, 2022, as supplemented on April 18, 2022, and August 4, 2022, NAC International, Inc. also requested to revise Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031. Amendment No. 12 amends the certificate of compliance as follows:

1. Adds a definition for concrete cask lid.
2. Revises the definition for concrete cask to exclude the lid.
3. Adds a definition for storage cask.
4. Provides alternate fabrication criteria and techniques for the concrete cask lid.

Revision 2 to Amendment Nos. 0 through 3 and Revision 1 to Amendments Nos. 4 through 9 revise the certificate of compliance to incorporate the changes made by Amendment 12.

As documented in the preliminary safety evaluation reports, the NRC performed safety evaluations of the proposed certificate of compliance amendment requests. The NRC determined that these amendments do not reflect a significant change in design or fabrication of the cask. Specifically, the NRC determined that the design of the casks would continue to maintain confinement, shielding, and criticality control in the event of each evaluated

accident condition. The NRC found there will be no significant change in the types or amounts of any effluent released, no significant increase in the individual or cumulative radiation exposure, and no significant increase in the potential for or consequences from radiological accidents. Therefore, any resulting occupational exposure or offsite dose rates from the implementation of Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 would remain well within the limits specified by 10 CFR part 20, ''Standards for Protection Against Radiation.''

The NRC determined that the amended NAC International, Inc. MAGNASTOR® Storage System cask design, when used under the conditions specified in the certificate of compliance, the technical specifications, and the NRC's regulations, will meet the requirements of 10 CFR part 72; therefore, adequate protection of public health and safety will continue to be reasonably assured. When this direct final rule becomes effective, persons who hold a general license under § 72.210 may, consistent with the license conditions under § 72.212, load spent nuclear fuel into NAC International, Inc. MAGNASTOR® Storage System casks that meet the criteria of the revised Amendment Nos. 0 through 9 and newly issued Amendment Nos. 11 and 12 to Certificate of Compliance No. 1031.

V. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995 (Pub. L. 104–113) requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this direct final rule, the NRC revises the NAC International, Inc. MAGNASTOR® Storage System design listed in § 72.214, ''List of approved spent fuel storage casks.'' This action does not constitute the establishment of a standard that contains generally applicable requirements.

VI. Agreement State Compatibility

Under the ''Agreement State Program Policy Statement'' approved by the Commission on October 2, 2017, and published in the **Federal Register** on October 18, 2017 (82 FR 48535), this rule is classified as Compatibility Category NRC—Areas of Exclusive NRC Regulatory Authority. The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the Atomic Energy Act of 1954, as amended, or the provisions of 10 CFR chapter I. Therefore, compatibility is not required for program elements in this category.

VII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885).

VIII. Environmental Assessment and Finding of No Significant Impact

Under the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC has determined that this direct final rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The NRC has made a finding of no significant impact on the basis of this environmental assessment.

A. The Action

The action is to amend § 72.214 to revise the NAC International, Inc. MAGNASTOR® Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment Nos. 11 and 12 and to include revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031.

B. The Need for the Action

This direct final rule amends the certificate of compliance for the NAC International, Inc. MAGNASTOR® Storage System design within the list of approved spent fuel storage casks to allow power reactor licensees to store spent fuel at reactor sites in casks with the approved modifications under a general license. Specifically, Amendment No. 11 revises the certificate of compliance to add a new concrete cask, transfer cask, fuel baskets and revised contents. Amendment No. 11 also adds a definition for the concrete cask lid, revises the definition for the concrete cask to exclude the lid, adds a definition for the storage cask, and provides alternate fabrication criteria and techniques for the concrete cask lid. Amendment No. 12 and the revisions to Amendment Nos. 0 through 9 add definitions for the storage cask and concrete cask lid, revise the definition of the concrete cask, and provide alternate fabrication criteria and techniques for the concrete cask lid to the certificate of compliance.

C. Environmental Impacts of the Action

On July 18,1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent fuel under a general license in cask designs approved by the NRC. The potential environmental impact of using NRC-approved storage casks was analyzed in the environmental assessment for the 1990 final rule. The environmental assessment for Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 tiers off of the environmental assessment for the July 18, 1990, final rule. Tiering on past environmental assessments is a standard process under the National Environmental Policy Act of 1969, as amended.

The NAC International, Inc. MAGNASTOR® Storage System is designed to mitigate the effects of design basis accidents that could occur during storage. Design basis accidents account for human-induced events and the most severe natural phenomena reported for the site and surrounding area. Postulated accidents analyzed for an independent spent fuel storage installation, the type of facility that a holder of a power reactor operating license would store spent fuel in casks in accordance with 10 CFR part 72, can include tornado winds and tornado-generated missiles, a design basis earthquake, a design basis flood, an accidental cask drop, lightning effects, fire, explosions, and other incidents.

This amendment does not reflect a significant change in design or fabrication of the cask. Because there are no significant design or process changes, any resulting occupational exposure or offsite dose rates from the implementation of Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 would remain well within the 10 CFR part 20 limits. The NRC has also determined that the design of the cask as modified by this rule would maintain confinement, shielding, and criticality control in the event of an accident. Therefore, the proposed changes will not result in any radiological or non-radiological environmental impacts that significantly differ from the environmental impacts evaluated in the environmental assessment supporting the July 18, 1990, final rule. There will be no significant change in the types or significant revisions in the amounts of any effluent released, no significant increase in the individual or cumulative radiation exposures, and no significant increase

in the potential for, or consequences from, radiological accidents. The NRC documented its safety findings in the preliminary safety evaluation report.

D. Alternative to the Action

The alternative to this action is to deny approval of Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 and not issue the direct final rule. Consequently, any 10 CFR part 72 general licensee that seeks to load spent nuclear fuel into the NAC International, Inc. MAGNASTOR® Storage System in accordance with the changes described in proposed Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9, including those licensees with fuel already loaded in casks that need these revisions, would have to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, interested licensees would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee. The environmental impacts would be the same as the proposed action.

E. Alternative Use of Resources

Approval of Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031 would result in no irreversible commitment of resources.

F. Agencies and Persons Contacted

No agencies or persons outside the NRC were contacted in connection with the preparation of this environmental assessment.

G. Finding of No Significant Impact

The environmental impacts of the action have been reviewed under the requirements in the National Environmental Policy Act of 1969, as amended, and the NRC's regulations in subpart A of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.'' Based on the foregoing environmental assessment, the NRC concludes that this direct final rule, ''List of Approved Spent Fuel Storage Casks: NAC International, Inc. MAGNASTOR® Storage System, Certificate of Compliance No. 1031, Amendment Nos. 11 and 12 and Revisions to Amendment Nos. 0 through 9,'' will not have a significant effect on the human environment. Therefore, the NRC has determined that an environmental impact statement is not necessary for this direct final rule.

IX. Paperwork Reduction Act Statement

This direct final rule does not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Existing collections of information were approved by the Office of Management and Budget, approval number 3150–0132.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid Office of Management and Budget control number.

X. Regulatory Flexibility Certification

Under the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the NRC certifies that this direct final rule will not, if issued, have a significant economic impact on a substantial number of small entities. This direct final rule affects only nuclear power plant licensees and NAC International, Inc. These entities do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards established by the NRC (§ 2.810).

XI. Regulatory Analysis

On July 18, 1990 (55 FR 29181), the NRC issued an amendment to 10 CFR part 72 to provide for the storage of spent nuclear fuel under a general license in cask designs approved by the NRC. Any nuclear power reactor licensee can use NRC-approved cask designs to store spent nuclear fuel if (1) it notifies the NRC in advance; (2) the spent fuel is stored under the conditions specified in the cask's certificate of compliance; and (3) the conditions of the general license are met. A list of NRC-approved cask designs is contained in § 72.214. On November 21, 2008 (73 FR 70587), the NRC issued an amendment to 10 CFR part 72 that approved the NAC International, Inc. MAGNASTOR® Storage System design by adding it to the list of NRC-approved cask designs in § 72.214.

On July 14, 2020, and as supplemented on August 23, 2021, January 11, 2022, March 18, 2022, April 18, 2022, and July 15, 2022, NAC International, Inc. submitted a request for Amendment No. 11 to amend the MAGNASTOR® Storage System. On January 24, 2022, and as supplemented on March 18, 2022 and April 18, 2022, NAC International, Inc. submitted a request for Amendment No. 12 to amend the MAGNASTOR® Storage System. Lastly, on March 18, 2022, and as supplemented on April 18, 2022 and August 4, 2022, NAC International, Inc. submitted a request to revise Amendment Nos. 0 through 9 of the MAGNASTOR® Storage System. All of these changes are described in Section IV, ''Discussion of Changes,'' of this document.

The alternative to this action is to withhold approval of Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 and to require any 10 CFR part 72 general licensee seeking to load spent nuclear fuel into the NAC International, Inc. MAGNASTOR® Storage System under the changes described in Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to request an exemption from the requirements of §§ 72.212 and 72.214. Under this alternative, each interested 10 CFR part 72 licensee would have to prepare, and the NRC would have to review, a separate exemption request, thereby increasing the administrative burden upon the NRC and the costs to each licensee.

Approval of this direct final rule is consistent with previous NRC actions. Further, as documented in the preliminary safety evaluation reports and environmental assessment, this direct final rule will have no adverse effect on public health and safety or the environment. This direct final rule has no significant identifiable impact or benefit on other government agencies. Based on this regulatory analysis, the NRC concludes that the requirements of this direct final rule are commensurate with the NRC's responsibilities for public health and safety and the common defense and security. No other available alternative is believed to be as satisfactory; therefore, this action is recommended.

XII. Backfitting

The NRC has determined that this direct final rule does not constitute backfitting under 10 CFR part 72. Certificate of compliance holders like NAC International, Inc. are not within the scope of the backfit rule in § 72.62. Additionally, Amendment Nos. 11 and 12 are outside the scope of backfitting because they apply only to new casks and are voluntary for existing users. Although general licensees that are affected by the revisions to Amendment Nos. 0–9 are within the scope of the backfitting regulations in § 72.62, the affected licensees have stated that they will voluntarily adopt the revisions, and therefore, this direct final rule does not constitute a backfit for those licensees.

This direct final rule revises Certificate of Compliance No. 1031 for the MAGNASTOR® Storage System, as currently listed in § 72.214, to add Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9. Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031 for the NAC International, Inc. MAGNASTOR® Storage System were initiated by NAC International, Inc. and were not submitted in response to new NRC requirements or an NRC request for amendment. Amendment Nos. 11 and 12 apply only to new casks fabricated and used under Amendment Nos. 11 and 12. These changes do not affect existing users of the NAC International, Inc. MAGNASTOR® Storage System, and the current Amendment No. 10 continues to be effective for existing users. While current users of this storage system may comply with the new requirements in Amendment Nos. 11 and 12, this would be a voluntary decision on the part of current users. Although NAC International, Inc. has manufactured casks under the existing Certificate of Compliance No. 1031, Amendment Nos. 0 through 9, NAC International, Inc., as the certificate of compliance holder, is not within the scope of backfitting under 10 CFR 72.62.

General licensees are entities that are within the scope of the backfitting regulations in 10 CFR 72.62. However, according to NAC International, Inc., no general licensees have purchased the MAGNASTOR® Storage Systems under Certificate of Compliance No. 1031, Amendment Nos. 0 through 5 and Amendment No. 8, that are, in part, the subject of these revisions. Therefore, the changes in Certificate of Compliance No. 1031, Amendment Nos. 0 through 5 and Amendment No. 8, that are approved in this direct final rule, do not fall within the definition of backfitting under 10 CFR 72.62.

Dominion Energy Kewaunee at the Kewaunee independent spent fuel storage installation and ZionSolutions at its independent spent fuel storage installation are two general licensees using Amendment No. 6 that could be affected by issuance of Revision 1 to Amendment No. 6. In its letter to NAC International, Inc., Dominion Energy Kewaunee stated that it would voluntarily adopt Revision 1 to Amendment No. 6. ZionSolutions stated it intends to rely on issuance of Revision 1 to Amendment No. 6 and Amendment No. 12 to reconcile the lid licensing issue and close the open action in its corrective action program. The NRC interprets these letters to mean that the licensees will voluntarily comply with Revision 1 to Amendment No. 6. Therefore, the issuance of Revision 1 to Amendment No. 6 does not fall within the definition of backfitting under 10 CFR 72.62.

Arizona Public Service Company at the Palo Verde independent spent fuel storage installation and Duke Energy at the Catawba and McGuire independent spent fuel storage installations are general licensees using Amendment No. 7 that could be affected by issuance of Revision 1 to Amendment No. 7. In its letter to NAC International, Inc., both Arizona Public Service Company and Duke Energy stated that they intend to implement Revision 1 to Amendment No. 7. The NRC interprets these letters to mean that the licensees will voluntarily comply with Revision 1 to Amendment No. 7. Therefore, issuance of Revision 1 to Amendment No. 7 does not fall within the definition of backfitting under 10 CFR 72.62.

Constellation Energy Generation at its Three Mile Island Unit 1 independent spent fuel storage installation is the only general licensee using Amendment No. 9 that could be affected by issuance of Revision 1 to Amendment No. 9. In its letter to NAC International, Inc., Constellation Energy Generation stated that it intends to implement Revision 1 to Amendment No. 9 in a timely manner after issuance of the revision. The NRC interprets this letter to mean that the licensee will voluntarily comply with Revision 1 to Amendment No. 9. Therefore, issuance of Revision 1 to Amendment No. 9 does not fall within the definition of backfitting under 10 CFR 72.62.

For these reasons, Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031 do not constitute backfitting under § 72.62. Accordingly, the NRC does not need to prepare a backfit analysis for this rulemaking.

XIII. Congressional Review Act

This direct final rule is not a rule as defined in the Congressional Review Act.

XIV. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS accession No./ **Federal Register** citation
Documents Related to Initial Certificate (Amendment No. 0), Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2	ML22220A151
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A152
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A154
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 1, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2	ML22220A156
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A157
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A158

Document	ADAMS accession No./ **Federal Register** citation
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 2, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2	ML22220A159
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A160
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A161
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 3, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2	ML22220A163
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A164
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A165
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 4, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1	ML22220A166
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A167
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A168
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 5, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1	ML22220A169
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A170
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A171
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197

Document	ADAMS accession No./ **Federal Register** citation
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 6, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1	ML22220A172
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A173
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A174
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 7, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1	ML22220A175
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A176
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A177
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 8, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1	ML22220A178
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A179
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A180
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 9, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1	ML22220A181
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A182
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A183
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment No. 9.	ML22220A184
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 11	
Proposed Certificate of Compliance No. 1031, Amendment No. 11	ML22220A185
Proposed Certificate of Compliance No. 1031, Amendment No. 11, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A186

Document	ADAMS accession No./ **Federal Register** citation
Proposed Certificate of Compliance No. 1031, Amendment No. 11, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A187
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Amendment No. 11.	ML22220A188
NAC International, Submission of a Request to Amend Certificate of Compliance No. 1031 for the NAC International MAGNASTOR® Cask System, Docket No. 72–1031, dated July 14, 2020.	ML20210M079 (package)
NAC International, Submission of RAI Responses for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated August 23, 2021.	ML21242A053 (package)
NAC International, Submission of Supplemental Information to the RAI for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated January 11, 2022.	ML22018A059
NAC International, Submission of Supplemental Information to the RAI for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated July 15, 2022.	ML22196A022 (package)
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
Documents Related to Amendment No. 12	
Proposed Certificate of Compliance No. 1031, Amendment No. 12	ML22220A189
Proposed Certificate of Compliance No. 1031, Amendment No. 12, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A190
Proposed Certificate of Compliance No. 1031, Amendment No. 12, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A191
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Amendment No. 12.	ML22220A192
NAC International, Submission of an Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated January 24, 2022.	ML22024A374
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197
Other Documents	
User Need Memorandum for Amendment Nos. 11 and 12, and Revision to Amendment Nos. 0 through 9 for the MAGNASTOR® Storage System, dated March 7, 2023.	ML22220A150
Final Rule, "Storage of Spent Fuel in NRC-Approved Storage Casks at Power Reactor Sites," published July 18, 1990.	55 FR 29181
Final Rule, "List of Approved Spent Fuel Storage Casks: MAGNASTOR Addition," published November 21, 2008	73 FR 70587
Revision to Policy Statement, "Agreement State Program Policy Statement; Correction," published October 18, 2017.	82 FR 48535
Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998	63 FR 31885

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2023–0085. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2023–0085); (2) click the "Subscribe" link; and (3) enter an email address and click on the "Subscribe" link.

List of Subjects in 10 CFR Part 72

Administrative practice and procedure, Hazardous waste, Indians, Intergovernmental relations, Nuclear energy, Penalties, Radiation protection, Reporting and recordkeeping requirements, Security measures, Spent fuel, Whistleblowing.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; the Nuclear Waste Policy Act of 1982, as amended; and 5 U.S.C. 552 and 553; the NRC is adopting the following amendments to 10 CFR part 72:

PART 72—LICENSING REQUIREMENTS FOR THE INDEPENDENT STORAGE OF SPENT NUCLEAR FUEL, HIGH-LEVEL RADIOACTIVE WASTE, AND REACTOR-RELATED GREATER THAN CLASS C WASTE

■ 1. The authority citation for part 72 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 51, 53, 57, 62, 63, 65, 69, 81, 161, 182, 183, 184, 186, 187, 189, 223, 234, 274 (42 U.S.C. 2071, 2073, 2077, 2092, 2093, 2095, 2099, 2111, 2201, 2210e, 2232, 2233, 2234, 2236, 2237, 2238, 2273, 2282, 2021); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); National Environmental Policy Act of 1969 (42 U.S.C. 4332); Nuclear Waste Policy Act of 1982, secs. 117(a), 132, 133, 134, 135, 137, 141, 145(g), 148, 218(a) (42 U.S.C. 10137(a), 10152, 10153, 10154, 10155, 10157, 10161, 10165(g), 10168, 10198(a)); 44 U.S.C. 3504 note.

■ 2. In § 72.214, Certificate of Compliance No. 1031 is revised to read as follows:

§ 72.214 List of approved spent fuel storage casks.

* * * * *

Certificate Number: 1031.

Initial Certificate Effective Date: February 4, 2009, superseded by Initial Certificate, Revision 1, on February 1,

2016, superseded by Initial Certificate, Revision 2, on October 16, 2023.

Amendment Number 1 Effective Date: August 30, 2010, superseded by Amendment Number 1, Revision 1, on February 1, 2016, superseded by Amendment Number 1, Revision 2, on October 16, 2023.

Amendment Number 2 Effective Date: January 30, 2012, superseded by Amendment Number 2, Revision 1, on February 1, 2016, superseded by Amendment Number 2, Revision 2, on October 16, 2023.

Amendment Number 3 Effective Date: July 25, 2013, superseded by Amendment Number 3, Revision 1, on February 1, 2016, superseded by Amendment Number 3, Revision 2, on October 16, 2023.

Amendment Number 4 Effective Date: April 14, 2015, superseded by Amendment Number 4, Revision 1, on October 16, 2023.

Amendment Number 5 Effective Date: June 29, 2015, superseded by Amendment Number 5, Revision 1, on October 16, 2023.

Amendment Number 6 Effective Date: December 21, 2016, superseded by Amendment Number 6, Revision 1, on October 16, 2023.

Amendment Number 7 Effective Date: August 21, 2017, as corrected (ADAMS Accession No. ML19045A346), superseded by Amendment Number 7, Revision 1, on October 16, 2023.

Amendment Number 8, Effective Date: March 24, 2020, superseded by Amendment Number 8, Revision 1, on October 16, 2023.

Amendment Number 9, Effective Date: December 7, 2020, superseded by Amendment Number 9, Revision 1, on October 16, 2023.

Amendment Number 10, Effective Date: January 18, 2023.

Amendment Number 11, Effective Date: October 16, 2023.

Amendment Number 12, Effective Date: October 16, 2023.

SAR Submitted by: NAC International, Inc.

SAR Title: Final Safety Analysis Report for the MAGNASTOR® System.

Docket Number: 72–1031.

Certificate Expiration Date: February 4, 2029.

Model Number: MAGNASTOR®.

* * * * *

Dated: July 18, 2023.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2023–16138 Filed 7–28–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–0427; Project Identifier MCAI–2022–01370–T; Amendment 39–22488; AD 2023–13–03]

RIN 2120–AA64

Airworthiness Directives; Airbus SAS Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all Airbus SAS Model A318, A319, A320, and A321 series airplanes. This AD was prompted by reports where the passenger door external handle mechanism was not retrieving its normal, flush position when the door was being closed. This AD requires a one-time cleaning and lubrication of the external door handle mechanism of each affected door, and limits the installation of affected parts, as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 5, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 5, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–0427; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

• For EASA material incorporated by reference in this AD, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

• You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2023–0427.

FOR FURTHER INFORMATION CONTACT: Timothy Dowling, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206–231–3667; email *Timothy.P.Dowling@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all Airbus SAS Model A318–111, A318–112, A318–121, A318–122, A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A319–151N, A319–153N, A319–171N, A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, A320–233, A320–251N, A320–252N, A320–253N, A320–271N, A320–272N, A320–273N, A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, A321–232, A321–251N, A321–251NX, A321–252N, A321–252NX, A321–253N, A321–253NX, A321–271N, A321–271NX, A321–272N, and A321–272NX airplanes. The NPRM published in the **Federal Register** on March 8, 2023 (88 FR 14298). The NPRM was prompted by AD 2022–0213R1, dated November 8, 2022, issued by EASA, which is the Technical Agent for the Member States of the European Union (EASA AD 2022–0213R1) (also referred to as the MCAI). The MCAI states one operator has reported two cases of a passenger/flight crew door external handle flap remained stuck in an intermediate or fully pushed position (not flush with the door skin) on two recently delivered Model A320 series airplanes after the door was opened from outside. With the external handle flap in this intermediate position, in one of the reported cases, the operator was not able to open the door normally from inside. Subsequent investigation determined that on the production line of one door supplier, corrosion protection compound (CPC) was inadvertently applied to the movable parts of the mechanism during production. The CPC, when applied to these parts leads to a sticky effect and prevents the passenger door external handle flap from moving to the closed position, which is flush with the fuselage skin.

In the NPRM, the FAA proposed to require a one-time cleaning and

lubrication of the external door handle mechanism of each affected door, and to limit the installation of affected parts, as specified in EASA AD 2022–0213R1. The FAA is issuing this AD to address external door handle mechanisms coated with CPC preventing the passenger door external handle flap from moving to the closed position, which if not addressed, could inhibit opening the door from the inside, or allow the door to open, automatically disarming the slide/raft, which would result in its non-automatic deployment. Both scenarios could delay a safe evacuation of airplane occupants during an emergency.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–0427.

Discussion of Final Airworthiness Directive

Comments

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

The FAA received additional comments from Delta Air Lines (DAL) and United Airlines (UAL). The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Add an Exception To Allow Maintenance Records Review

DAL requested that the NPRM be revised to add an exception to allow a records review by DAL Engineering to determine the airplanes with affected passenger doors and to identify if any external control handle lubrication had already been accomplished prior to the inspection by DAL maintenance. DAL stated that its maintenance department is not typically responsible for performing records review as part of their responsibilities, as this is a function of the engineering department.

The FAA disagrees with adding an exception, since accomplishment of Paragraph 5.6, Steps (1) and (2) do not require review of maintenance records nor do they require maintenance personnel to conduct the review if DAL decides to use maintenance records to accomplish the AD actions as the DAL comment suggests. The FAA agrees that a review of the airplane maintenance records by engineering is acceptable to determine if an aircraft has an affected door or to verify control handle lubrication has already been accomplished. The FAA has not changed this AD in this regard.

Request To Revise Applicability To Include Affected Doors

UAL requested that paragraph (c) of the proposed AD be revised to include affected passenger doors to address part interchangeability. UAL stated that inclusion of the affected passenger door part numbers will help operators to identify the potential installation of the impacted doors within their fleet using the Illustrated Parts Catalog (IPC) for configuration control.

The FAA disagrees with the need to add door part numbers to this AD. The service information specified in EASA AD 2022–0213R1 identifies the suspect passenger doors by serial numbers. Further, the FAA agrees that the movement of doors within an operator's fleet is possible so this AD, as written, addresses the issue of rotability in two ways. First, the applicability in paragraph (c) of this AD includes all Airbus SAS Model A318, A319, A320, and A321 series airplanes. Second, the requirements of this AD include a parts installation limitation, as specified in EASA AD 2022–0213R1. Therefore, the FAA has not changed this AD in this regard.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, this AD is adopted as proposed in the NPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0213R1 specifies procedures for cleaning and lubricating the movable parts of the external passenger door handle mechanism of affected doors. EASA AD 2022–0213R1 also limits the installation of affected parts. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

Costs of Compliance

The FAA estimates that this AD affects 1,864 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Up to 4 work-hours × $85 per hour = $340	$50	Up to $390	Up to $726,960.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities

under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–13–03 Airbus SAS: Amendment 39–22488; Docket No. FAA–2023–0427; Project Identifier MCAI–2022–01370–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 5, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all Airbus SAS airplanes identified in paragraphs (c)(1) through (4) of this AD, certificated in any category.

(1) Model A318–111, A318–112, A318–121, and A318–122 airplanes.

(2) Model A319–111, A319–112, A319–113, A319–114, A319–115, A319–131, A319–132, A319–133, A319–151N, A319–153N, and A319–171N airplanes.

(3) Model A320–211, A320–212, A320–214, A320–216, A320–231, A320–232, A320–233, A320–251N, A320–252N, A320–253N, A320–271N, A320–272N, and A320–273N airplanes.

(4) Model A321–111, A321–112, A321–131, A321–211, A321–212, A321–213, A321–231, A321–232, A321–251N, A321–251NX, A321–252N, A321–252NX, A321–253N, A321–253NX, A321–271N, A321–271NX, A321–272N, and A321–272NX airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 52, Doors.

(e) Unsafe Condition

This AD was prompted by reports where the passenger door external handle mechanism was not allowing the flap handle to return to its normal, flush position when the door was being closed. Subsequent investigation concluded corrosion protection compound (CPC) was inadvertently applied to the movable parts of the mechanism during production. The CPC prevents the handle flap from moving to the closed position, flush with the fuselage skin. The unsafe condition, if not addressed, could inhibit opening the door from the inside, or allow the door to open, automatically disarming the slide/raft, which would result in its non-automatic deployment. Both scenarios could delay a safe evacuation of airplane occupants during an emergency.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0213R1, dated November 8, 2022 (EASA AD 2022–0213R1).

(h) Exceptions to EASA AD 2022–0213R1

(1) Where EASA AD 2022–0213R1 refers to November 3, 2022 (the effective of EASA AD 2022–0213, dated October 20, 2022), this AD requires using the effective date of this AD.

(2) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0213R1.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(3) *Required for Compliance (RC):* Except as required by paragraph (i)(2) of this AD, if any service information referenced in EASA AD 2022–0213R1 contains paragraphs that are labeled as RC, the instructions in RC paragraphs, including subparagraphs under an RC paragraph, must be done to comply with this AD; any paragraphs, including subparagraphs under those paragraphs, that are not identified as RC are recommended. The instructions in paragraphs, including subparagraphs under those paragraphs, not identified as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the instructions identified as RC can be done and the airplane can be put back in an airworthy condition. Any substitutions or changes to instructions identified as RC require approval of an AMOC.

(j) Additional Information

For more information about this AD, contact Timothy Dowling, Aerospace Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 206–231–3667; email *Timothy.P.Dowling@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0213R1, dated November 8, 2022.

(ii) [Reserved]

(3) For EASA AD 2022–0213R1, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

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

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

Issued on June 30, 2023.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–16095 Filed 7–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1163; Project Identifier MCAI–2022–00571–T; Amendment 39–22487; AD 2023–13–02]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.; Embraer S.A.) Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for certain Embraer S.A. Model ERJ 170 airplanes. This AD was prompted by reports indicating that certain flight control electrical harnesses were routed incorrectly, providing inadequate separation from other electrical harness installations. This AD requires an inspection of certain flight control electrical harnesses for incorrect routing, and modifying any incorrect electrical harness installations, as specified in an Agência Nacional de Aviação Civil (ANAC) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 5, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of September 5, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1163; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this material on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available in the AD docket at *regulations.gov* under Docket No. FAA–2022–1163.

FOR FURTHER INFORMATION CONTACT: Joshua K. Bragg, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 817–222–5366; email: *joshua.k.bragg@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Embraer S.A. Model ERJ 170 airplanes. The NPRM published in the **Federal Register** on September 15, 2022 (87 FR 56598). The NPRM was prompted by AD 2022–04–01, effective April 29, 2022, issued by ANAC, which is the aviation authority for Brazil (ANAC AD 2022–04–01) (also referred to as the MCAI). The MCAI states that certain flight control electrical harnesses were routed incorrectly, providing inadequate separation from other electrical harness installations.

In the NPRM, the FAA proposed to require inspecting certain flight control electrical harnesses for incorrect routing, and modifying any incorrect electrical harness installations, as specified in ANAC AD 2022–04–01.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2022–1163.

The FAA issued a supplemental notice of proposed rulemaking (SNPRM) to amend 14 CFR part 39 by adding an AD that would apply to certain Embraer S.A. Model ERJ 170 airplanes. The SNPRM published in the **Federal Register** on February 24, 2023 (88 FR 11830). The SNPRM was prompted by reports indicating that certain flight control electrical harnesses were routed incorrectly, providing inadequate separation from other electrical harness installations. In the SNPRM, the FAA proposed to require inspecting certain flight control electrical harnesses for incorrect routing, and modifying any incorrect electrical harness installations. The FAA is issuing this AD to address the incorrect routing of flight control electrical harnesses near critical fuel quantity indication harnesses, which could possibly result in fuel tank ignition and subsequent loss of the airplane.

Discussion of Final Airworthiness Directive

Comments

The FAA received a comment from Air Line Pilots Association, International (ALPA), who supported the SNPRM without change.

The FAA received additional comments from two commenters, including Embraer and Horizon Air. The following presents the comments received on the SNPRM and the FAA's response to each comment.

Requests for Increased Compliance Time and Later Date for Correction

Embraer requested that the FAA allow an increase in the compliance time and to allow the correction to be done at a later date. According to Embraer, because this inspection and subsequent correction of the wiring harnesses cannot fit within a basic check, operators plan to add it to the heavy maintenance visits, during which these accesses are already open. However, the service information and the proposed AD do not allow for inspecting to be done at one opportunity and correction to be done at a later date.

The FAA does not agree to the requests to revise the compliance time and allow correction to be done later. ANAC, as the state of design authority, conducted a safety analysis and determined that a 12-month compliance time is appropriate to mitigate the identified unsafe condition and did not allow for correction to be done later. The FAA concurs with ANAC's assessment. However, under the provisions specified in paragraph (i)(1) of this AD, operators may request an alternative method of compliance (AMOC) to use a different compliance time, if the proposed AMOC provides an acceptable level of safety. This AD has not been changed with regard to this request.

Request To Increase the Estimated Work-Hours

Embraer requested an increase in the total number of estimated work-hours for the required actions. The commenter noted that the actual work-hours required for the actions have proven to be greater than the estimate given in the proposed AD.

The FAA agrees with the request because the agency has determined that the total work-hours required exceed the previous estimate. The FAA has increased the estimated total work-hours from 8 to 16.

Request To Correct Typographical Error

Horizon Air requested that a correction be made in paragraph (i)(3) of the proposed AD. The commenter noted that the reference to paragraph (j)(3)(i) should be to paragraph (i)(3)(i).

The FAA agrees with the request. The FAA has corrected the typographical error in this AD.

Conclusion

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of

Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA reviewed the relevant data, considered the comments received, and determined that air safety requires adopting this AD as proposed. Accordingly, the FAA is issuing this AD to address the unsafe condition on this product. Except for minor editorial changes, and any other changes described previously, this AD is adopted as proposed in the SNPRM. None of the changes will increase the economic burden on any operator.

Related Service Information Under 1 CFR Part 51

ANAC AD 2022–04–01R1 specifies procedures for inspecting the installation of flight control electrical harnesses W126 and W127 for incorrect routing and modifying any incorrect electrical harness installations. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

Costs of Compliance

The FAA estimates that this AD affects 701 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
6 work-hours × $85 per hour = $510	$0	$510	$357,510

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
10 work-hours × $85 per hour = $850	$0	$850

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–13–02 Embraer S.A. (Type Certificate Previously Held by Yaborã Indústria Aeronáutica S.A.; Embraer S.A.): Amendment 39–22487; Docket No. FAA–2022–1163; Project Identifier MCAI–2022–00571–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 5, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. (Type Certificate previously held by Yaborã Indústria Aeronáutica S.A.; Embraer S.A.) Model ERJ 170–100 LR, –100 STD, –100 SE, and –100 SU airplanes; and Model ERJ 170–200 LR, –200 SU, –200 STD, and –200 LL airplanes, certificated in any category, as identified in Agência Nacional de Aviação Civil (ANAC) AD 2022–04–01R1, effective October 31, 2022 (ANAC AD 2022–04–01R1).

(d) Subject

Air Transport Association (ATA) of America Code 27, Flight controls.

(e) Unsafe Condition

This AD was prompted by reports indicating that certain flight control electrical harnesses were routed incorrectly, providing inadequate separation from other electrical harness installations. The FAA is issuing this AD to address the incorrect routing of flight control electrical harnesses near critical fuel quantity indication harnesses, which could possibly result in fuel tank ignition and subsequent loss of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, ANAC AD 2022–04–01R1.

(h) Exceptions to ANAC AD 2022–04–01R1

(1) Where ANAC AD 2022–04–01R1 refers to April 29, 2022 (the effective date of ANAC AD 2022–04–01), this AD requires using the effective date of this AD.

(2) Where ANAC AD 2022–04–01R1 refers to its effective date, this AD requires using the effective date of this AD.

(3) Where ANAC AD 2022–04–01R1 refers to August 3, 2022 (the Revision 02 date of Embraer Service Bulletin), the correct date is August 5, 2022.

(4) Paragraph (c) of ANAC AD 2022–04–01R1 does not apply to this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or ANAC; or ANAC's authorized Designee. If approved by the ANAC Designee, the approval must include the Designee's authorized signature.

(3) *Required for Compliance (RC):* Except as specified by paragraph (i)(2) of this AD: if any service information contains steps that are labeled as RC, the provisions of paragraphs (i)(3)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(j) Additional Information

For more information about this AD, contact Joshua K. Bragg, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone 817–222–5366; email: *joshua.k.bragg@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) Agência Nacional de Aviação Civil (ANAC) AD 2022–04–01R1, effective October 31, 2022.

(ii) [Reserved]

(3) For ANAC AD 2022–04–01R1, contact ANAC, Aeronautical Products Certification Branch (GGCP), Rua Dr. Orlando Feirabend Filho, 230—Centro Empresarial Aquarius—Torre B—Andares 14 a 18, Parque Residencial Aquarius, CEP 12.246–190—São José dos Campos—SP, Brazil; telephone 55 (12) 3203–6600; email *pac@anac.gov.br;* website *anac.gov.br/en/.* You may find this ANAC AD on the ANAC website at *sistemas.anac.gov.br/certificacao/DA/DAE.asp.*

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

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

Issued on July 21, 2023.

Victor Wicklund,

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

[FR Doc. 2023–16164 Filed 7–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1487; Project Identifier MCAI–2022–01626–T; Amendment 39–22504; AD 2023–14–04]

RIN 2120–AA64

Airworthiness Directives; Fokker Services B.V. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; request for comments.

SUMMARY: The FAA is superseding Airworthiness Directive (AD) 2020–09–11 and AD 2022–21–12, which applied to all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. AD 2020–09–11 and AD 2022–21–12 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. Since the FAA issued AD 2022–21–12, new or more restrictive tasks and limitations have been introduced. This AD continues to require the actions of AD 2022–21–12, and also requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations; as specified in a European Union Aviation Safety Agency (EASA) AD, which is incorporated by reference. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective August 15, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of August 15, 2023.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of December 1, 2022 (87 FR 68621, November 16, 2022).

The FAA must receive comments on this AD by September 14, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1487; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For material incorporated by reference in this AD, contact EASA,

Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*

• You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available at *regulations.gov* under Docket No. FAA–2023–1487.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3225; email *dan.rodina@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written data, views, or arguments about this final rule. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–1487; Project Identifier MCAI–2022–01626–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the final rule, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this final rule because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this AD contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this AD, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this AD. Submissions containing CBI should be sent to Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3225; email *dan.rodina@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The FAA issued AD 2022–21–12, Amendment 39–22211 (87 FR 68621, November 16, 2022) (AD 2022–21–12), for all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. AD 2022–21–12 was prompted by an MCAI originated by EASA, which is the Technical Agent for the Member States of the European Union. EASA issued AD 2022–0027, dated February 18, 2022 (EASA AD 2022–0027), to correct an unsafe condition.

AD 2022–21–12 required revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations. The FAA issued AD 2022–21–12 to prevent reduced structural integrity of the airplane.

Actions Since AD 2022–21–12 Was Issued

Since the FAA issued AD 2022–21–12, EASA superseded AD 2022–0027 and issued EASA AD 2022–0260, dated December 20, 2022 (EASA AD 2022–0260) (also referred to as the MCAI), to correct an unsafe condition for all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes. The MCAI states that new or more restrictive airworthiness limitations have been developed.

EASA AD 2022–0027, dated February 18, 2022, superseded EASA AD 2020–0024, dated February 13, 2020 (which corresponds to FAA AD 2020–09–11, Amendment 39–19907 (85 FR 30592, May 20, 2020) (AD 2020–09–11). AD 2020–09–11 requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations (a prior revision of the airworthiness limitations section (ALS) document required by AD 2022–21–12). The FAA has therefore determined that this AD should also supersede AD 2020–09–11.

The FAA is issuing this AD to address reduced structural integrity of the airplane. You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1487.

Related Service Information Under 1 CFR Part 51

EASA AD 2022–0260 specifies new or more restrictive airworthiness limitations for airplane structures and safe life limits.

This AD also requires EASA AD 2022–0027, dated February 18, 2022, which the Director of the Federal Register approved for incorporation by reference as of December 1, 2022 (87 FR 68621, November 16, 2022).

This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI referenced above. The FAA is issuing this AD after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

AD Requirements

This AD retains the requirements of AD 2022–21–12. This AD also requires revising the existing maintenance or inspection program, as applicable, to incorporate new or more restrictive airworthiness limitations, which are specified in EASA AD 2022–0260 described previously, as incorporated by reference. Any differences with EASA AD 2022–0260 are identified as exceptions in the regulatory text of this AD.

This AD requires revisions to certain operator maintenance documents to include new actions (e.g., inspections). Compliance with these actions is required by 14 CFR 91.403(c). For airplanes that have been previously modified, altered, or repaired in the areas addressed by this AD, the operator may not be able to accomplish the actions described in the revisions. In this situation, to comply with 14 CFR 91.403(c), the operator must request approval for an alternative method of compliance (AMOC) according to paragraph (m)(1) of this AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of

information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA retains the IBR of EASA AD 2022–0027 and incorporates EASA AD 2022–0260 by reference in this AD. This AD requires compliance with EASA AD 2022–0027 and EASA AD 2022–0260 through that incorporation, except for any differences identified as exceptions in the regulatory text of this AD. Using common terms that are the same as the heading of a particular section in EASA AD 2022–0027 or EASA AD 2022–0260 does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions and compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2022–0027 or EASA AD 2022–0260. Service information required by EASA AD 2022–0027 and EASA AD 2022–0260 for compliance will be available at *regulations.gov* under Docket No. FAA–2023–1487 after this AD is published.

Airworthiness Limitation ADs Using the New Process

The FAA's process of incorporating by reference MCAI ADs as the primary source of information for compliance with corresponding FAA ADs has been limited to certain MCAI ADs (primarily those with service bulletins as the primary source of information for accomplishing the actions required by the FAA AD). However, the FAA is now expanding the process to include MCAI ADs that require a change to airworthiness limitation documents, such as airworthiness limitation sections.

For these ADs that incorporate by reference an MCAI AD that changes airworthiness limitations, the FAA requirements are unchanged. Operators must revise the existing maintenance or inspection program, as applicable, to incorporate the information specified in the new airworthiness limitation document. The airworthiness limitations must be followed according to 14 CFR 91.403(c) and 91.409(e).

The previous format of the airworthiness limitation ADs included a paragraph that specified that no alternative actions (*e.g.,* inspections) or intervals may be used unless the actions and intervals are approved as an AMOC in accordance with the procedures specified in the AMOCs paragraph under ''Additional AD Provisions.'' This new format includes a ''New Provisions for Alternative Actions and Intervals'' paragraph that does not specifically refer to AMOCs, but operators may still request an AMOC to use an alternative action or interval.

FAA's Justification and Determination of the Effective Date

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

There are currently no domestic operators of these products. Accordingly, notice and opportunity for prior public comment are unnecessary, pursuant to 5 U.S.C. 553(b)(3)(B). In addition, for the forgoing reason, the FAA finds that good cause exists pursuant to 5 U.S.C. 553(d) for making this amendment effective in less than 30 days.

Regulatory Flexibility Act (RFA)

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

Costs of Compliance

Currently, there are no affected U.S.-registered airplanes. If an affected airplane is imported and placed on the U.S. Register in the future, the FAA provides the following cost estimates to comply with this AD:

The FAA has determined that revising the existing maintenance or inspection program takes an average of 90 work-hours per operator, although the agency recognizes that this number may vary from operator to operator. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), the FAA has determined that a per-operator estimate is more accurate than a per-airplane estimate.

The FAA estimates the total cost per operator for the new actions to be $7,650 (90 work-hours × $85 per work-hour).

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by:

■ a. Removing Airworthiness Directive (AD) 2020–09–11, Amendment 39–19907 (85 FR 30592, May 20, 2020) and AD 2022–21–12, Amendment 39–22211 (87 FR 68621, November 16, 2022); and

■ b. Adding the following new AD:

2023–14–04 Fokker Services B.V.: Amendment 39–22504; Docket No. FAA–2023–1487; Project Identifier MCAI–2022–01626–T.

(a) Effective Date

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

(b) Affected ADs

This AD replaces AD 2020–09–11, Amendment 39–19907 (85 FR 30592, May 20, 2020) (AD 2020–09–11) and AD 2022–21–12, Amendment 39–22211 (87 FR 68621, November 16, 2022) (AD 2022–21–12).

(c) Applicability

This AD applies to all Fokker Services B.V. Model F28 Mark 0070 and 0100 airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 05, Time Limits/Maintenance Checks.

(e) Unsafe Condition

This AD was prompted by a determination that new or more restrictive airworthiness limitations are necessary. The FAA is issuing this AD to address reduced structural integrity of the airplane.

(f) Compliance

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

(g) Retained Revision of the Existing Maintenance or Inspection Program, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2022–21–12, with no changes. Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, European Union Aviation Safety Agency (EASA) AD 2022–0027, dated February 18, 2022 (EASA AD 2022–0027). Accomplishing the revision of the existing maintenance or inspection program required by paragraph (j) of this AD terminates the requirements of this paragraph.

(h) Retained Exceptions to EASA AD 2022–0027, With No Changes

This paragraph restates the exceptions specified in paragraph (h) of AD 2022–21–12, with no changes.

(1) Where EASA AD 2022–0027 refers to its effective date, this AD requires using December 1, 2022 (the effective date of AD 2022–21–12).

(2) The requirements specified in paragraphs (1) and (2) of EASA AD 2022–0027 do not apply to this AD.

(3) Paragraph (3) of EASA AD 2022–0027 specifies revising ''the AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after December 1, 2022 (the effective date of AD 2022–21–12).

(4) The ''Remarks'' section of EASA AD 2022–0027 does not apply to this AD.

(i) Retained Restrictions on Alternative Actions and Intervals With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2022–21–12, with no changes. Except as required by paragraph (j) of this AD, after the existing maintenance or inspection program has been revised as required by paragraph (g) of this AD, no alternative actions (*e.g.,* inspections) or intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0027.

(j) New Revision of the Existing Maintenance or Inspection Program

Except as specified in paragraph (k) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, EASA AD 2022–0260, dated December 20, 2022 (EASA AD 2022–0260). Accomplishing the revision of the existing maintenance or inspection program required by this paragraph terminates the requirements of paragraph (g) of this AD.

(k) Exceptions to EASA AD 2022–0260

(1) This AD does not adopt the requirements specified in paragraphs (1) and (2) of EASA AD 2022–0260.

(2) Paragraph (3) of EASA AD 2022–0260 specifies revising ''the AMP'' within 12 months after its effective date, but this AD requires revising the existing maintenance or inspection program, as applicable, within 90 days after the effective date of this AD.

(3) The initial compliance time for doing the tasks specified in paragraph (3) of EASA 2022–0260 is at the applicable ''associated thresholds'' and ''limitations'' as incorporated by the requirements of paragraph (3) of EASA AD 2022–0260, or within 90 days after the effective date of this AD, whichever occurs later.

(4) This AD does not adopt the provisions specified in paragraphs (4) and (5) of EASA AD 2022–0260.

(5) This AD does not adopt the ''Remarks'' section of EASA AD 2022–0260.

(l) New Provisions for Alternative Actions and Intervals

After the existing maintenance or inspection program has been revised as required by paragraph (j) of this AD, no alternative actions (*e.g.,* inspections) and intervals are allowed unless they are approved as specified in the provisions of the ''Ref. Publications'' section of EASA AD 2022–0260.

(m) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the International Validation Branch, send it to the attention of the person identified in paragraph (n) of this AD. Information may be emailed to: *9-AVS-AIR-730-AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain instructions from a manufacturer, the instructions must be accomplished using a method approved by the Manager, International Validation Branch, FAA; or EASA; or Fokker Services B.V.'s EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(n) Additional Information

For more information about this AD, contact Dan Rodina, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone 206–231–3225; email *dan.rodina@faa.gov.*

(o) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on August 15, 2023.

(i) European Union Aviation Safety Agency (EASA) AD 2022–0260, dated December 20, 2022.

(ii) [Reserved]

(4) The following service information was approved for IBR on December 1, 2022 (87 FR 68621, November 16, 2022).

(i) European Union Aviation Safety Agency (EASA) AD 2022–0027, dated February 18, 2022.

(ii) Reserved

(5) For EASA ADs 2022–0027 and 2022–0260, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; telephone +49 221 8999 000; email *ADs@easa.europa.eu;* website *easa.europa.eu.* You may find these EASA ADs on the EASA website at *ad.easa.europa.eu.*

(6) You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. This material may be found in the AD docket at *regulations.gov* under Docket No. FAA–2023–1487.

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

Issued on July 8, 2023.

Michael Linegang,

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

[FR Doc. 2023–16096 Filed 7–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2022–1479; Project Identifier AD–2022–00703–T; Amendment 39–22497; AD 2023–13–12]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: The FAA is adopting a new airworthiness directive (AD) for all The Boeing Company Model 737–100, 737–200, 737–200C, 737–300, 737–400, 737–500, 737–600, 737–700, 737–700C, 737–800, 737–900, 737–900ER, 757–200, 757–200PF, 757–200CB, 757–300, 767–200, 767–300, 767–300F, and 767–400ER series airplanes. This AD was prompted by reports indicating premature aging of certain passenger chemical oxygen generators. This AD requires repetitively replacing affected chemical oxygen generators with serviceable parts. This AD also limits the installation of affected parts. The FAA is issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective September 5, 2023.

ADDRESSES:

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2022–1479; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, any comments received, and other information. The address for Docket Operations is U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Nicole S. Tsang, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3959; email: *nicole.s.tsang@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The FAA issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to all The Boeing Company Model 737–100, 737–200, 737–200C, 737–300, 737–400, 737–500, 737–600, 737–700, 737–700C, 737–800, 737–900, 737–900ER, 757–200, 757–200PF, 757–200CB, 757–300, 767–200, 767–300, 767–300F, and 767–400ER series airplanes. The NPRM published in the **Federal Register** on December 9, 2022 (87 FR 75528).

The NPRM was prompted by reports indicating premature aging of certain passenger chemical oxygen generators. In the NPRM, the FAA proposed to require repetitively replacing affected chemical oxygen generators with serviceable parts, and to limit the installation of affected parts. The FAA is issuing this AD to address the premature aging that resulted in the chemical oxygen generators failing to activate, which could fail to deliver oxygen during an emergency, possibly resulting in injury to the airplane occupants.

Discussion of Final Airworthiness Directive

Comments

The FAA received comments from the Air Line Pilots Association, International, and The Boeing Company. Both commenters supported the NPRM without change.

The FAA received additional comments from Delta Air Lines, American Airlines, United Airlines, and United Parcel Service. The following presents the comments received on the NPRM and the FAA's response to each comment.

Request To Clarify Service Life of Affected Parts

American Airlines requested clarification on why paragraph (i)(3) of the proposed AD allows chemical oxygen generators to remain in service longer than 10 years. American Airlines stated that paragraph (i)(3) of the proposed AD contradicts paragraph (h) of the proposed AD and leads to confusion.

The FAA agrees to clarify. Currently, there are units with a manufacturing date older than 10 years that are potentially installed on airplanes, and these units might be included in the group identified in paragraph (i)(3) of this AD. After the initial replacement required by paragraph (i)(3) of this AD, the introductory text to paragraph (i) of this AD requires operators to replace affected units before exceeding 10 years since date of manufacture. To determine the appropriate compliance time for paragraph (i)(3) of this AD, the FAA assessed the failure rate of the units, the number of suspect units, and the probability of an unsafe outcome. The FAA has not changed this AD in this regard.

Request To Remove the 30-Day Compliance Time for Inspection of Part Numbers

American Airlines and Delta Air Lines requested removing the 30-day compliance time for the inspection of the chemical oxygen generators part numbers. American Airlines stated that inspecting the part numbers alone does not provide any increase in safety and will severely disrupt the regular maintenance of the airplane with the potential to impact passengers if other work has to be postponed to meet a 30-day inspection requirement. Instead of requiring the 6-, 12-, and 24-month replacement, American Airlines suggested allowing 12 months to inspect and correct the units. Delta Air Lines recommended allowing operators to use existing methods to obtain chemical oxygen generator part numbers and dates of manufacture at a time that works within the needs of their operation rather than within 30 days. Delta Air Lines stated that the existing methods have already been reviewed by the operators' Certificate Management Office (CMO) and is FAA approved.

The FAA disagrees with the request to remove the 30-day compliance time for the part number inspection. The FAA disagrees with Delta Air Lines' recommendation to allow operators' existing methods to inspect the chemical oxygen generators part numbers and date of manufacture that work within the needs of their operation rather than within this AD's compliance time. The FAA also disagrees with replacing this AD's proposed compliance times with the American Airlines' proposed 12-month compliance time to inspect and correct units. The commenter did not provide justification to substantiate how a 12-month compliance time to inspect and correct units provides an acceptable level of safety. Passenger chemical oxygen generators identified in paragraph (i)(1) of this AD must be replaced sooner than the proposed 12-month compliance time. After considering all of the available information, the FAA determined that the compliance time, as proposed, represents an appropriate interval of time in which the required actions can be performed in a timely manner within the affected fleet, while still maintaining an adequate level of safety. When developing the compliance time, the FAA considered the estimated hours to complete the inspection and replacements and the availability of parts. There are provisions in paragraph (g) of this AD that allow review of the airplane maintenance records in lieu of

an inspection, provided the date of manufacture can be conclusively determined by that review. Under the provisions of paragraph (k) of this AD, operators may apply for an extension of the compliance times by providing rationale explaining why a compliance time extension provides an acceptable level of safety. The FAA has not changed this AD in this regard.

Request To Remove Inspection for Retired and Long-Term Storage Airplanes

American Airlines requested that inspection of retired airplanes or airplanes in long-term storage not be required until the airplane goes into service.

The FAA agrees that operators are not required to inspect retired airplanes because retired airplanes are not in service. And the FAA agrees that airplanes in long-term storage are not required to comply with the requirements of this AD until the airplane goes into service (14 CFR 39.7). If the compliance time has passed before a stored airplane is returned to service, it is not a violation. A violation occurs only if a product is operated that does not meet the requirements of an AD. Under the provisions of paragraph (k) of this AD, an operator who is unable to accomplish the inspection in this AD within the specified compliance time may request an alternative method of compliance (AMOC) to extend this time. The FAA has not changed this AD in this regard.

Request Six Months To Revise Manuals

American Airlines requested six months to revise applicable manuals.

The FAA disagrees with the request to require six months to revise applicable manuals. This AD requires only inspection of the chemical oxygen generator part numbers and replacement of chemical oxygen generators. This AD does not mandate revising applicable manuals. The FAA has not changed this AD in this regard.

Request Six Months To Purge Inventory

American Airlines requested six months to purge inventory of P/N 117080–XX chemical oxygen generators.

The FAA disagrees with the request to require six months to purge inventory of P/N 117080–XX chemical oxygen generators. This AD requires only inspection of the chemical oxygen generator part numbers and replacement of chemical oxygen generators. This AD does not mandate purging inventory of P/N 117080–XX chemical oxygen generators. The FAA has not changed this AD in this regard.

Request To Confirm Life Limit of AVOX Systems Part Number P/N 807218–03

American Airlines requested confirmation that FAA has determined AVOX Systems part number (P/N) 807218–03 does not have the same problems as P/N 117080–04 and continues to be an approved part number with a life of 15 years from the date of manufacture. AVOX Systems P/N 807218–03 has been qualified to both Boeing Spec S417T401–44 (or Drager P/N E71740–00) and Boeing Spec S417T401–60 (or Collins P/N 117080–04).

The FAA confirms that AVOX Systems P/N 807218–03 does not have the same problems as P/N 117080–04. The life limit for AVOX Systems P/N 807218–03 is 15 years from the date of manufacture. Because this AD does not address P/N 807218–03, no change to this AD is necessary.

Effect of Winglets on Accomplishment of the Proposed Actions

Aviation Partners Boeing stated that the installation of winglets per Supplemental Type Certificate (STC) ST00830SE, STC ST01219SE, STC ST01518SE, and STC ST01920SE on applicable Boeing models subject to the proposed AD does not affect compliance with the mandated actions.

The FAA agrees with the commenter that STC ST00830SE, STC ST01219SE, STC ST01518SE, and STC ST01920SE do not affect the ability to accomplish the actions required by this AD. The FAA has not changed this AD in this regard.

Request Use of Illustrated Parts Catalog To Determine Approved Part Numbers

Delta Air Lines requested clarification on how to determine whether a part number is approved. Paragraph (h)(2) of this AD does not have any provision to allow operators to determine if a part number is approved. Delta Air Lines assumed operators may use the airplane Illustrated Parts Catalog (IPC) to determine acceptable approved alternate parts.

The FAA confirms that operators may use the airplane IPC to determine acceptable approved part numbers. The FAA has not changed this AD in this regard.

Request To Define Acceptable Replacement Chemical Oxygen Generators

Delta Air Lines requested that paragraph (i) of the proposed AD be revised to explicitly state that chemical oxygen generators be replaced with serviceable units during the repetitive replacement.

The FAA agrees with the comment and has revised the introductory text to paragraph (i) of this AD accordingly.

Request To Limit Replacement Requirement Based on Date of Manufacture

Delta Air Lines suggested that paragraph (i) of the proposed AD be revised to state that no replacement is necessary for affected passenger chemical oxygen generators that have a date of manufacture in 2014 or later. Delta inferred that since these generators would have a manufacture date of 2014 or later, and therefore be within the new 10-year life limit, replacement would not be mandated per the proposed AD.

The FAA disagrees that units that have a date of manufacture in 2014 or later need not be replaced. The FAA has added paragraph (i)(4) of this AD to clarify that units with a date of manufacture in 2014 or later must be replaced before exceeding 10 years since the date of manufacture, with a 24-month grace period that will allow for timely and orderly replacement of units that are close to their 10-year life limit.

Request To Clarify Affected Airplanes

The United Parcel Service (UPS) Airlines requested limiting the proposed AD to apply only to the affected airplane models with part number 117080–02, 117080–03, or 117080–04 chemical oxygen generators installed. The commenter noted that the proposed AD would require accomplishment of paragraphs (g) and (i) on all of the airplane models covered by paragraph (c) of the proposed AD, even if an applicable airplane does not have part number 117080–02, 117080–03, or 117080–04 installed.

The FAA disagrees with the commenter's request. The FAA determined that the part number 117080–02, 117080–03, or 117080–04 chemical oxygen generators are rotable. This AD therefore applies to all airplanes of the affected models to ensure that no person installs a non-serviceable passenger chemical oxygen generator on an airplane that was initially delivered with an acceptable unit, thereby subjecting that airplane to the unsafe condition. The FAA has not changed this AD in this regard.

Additional Change to AD

The compliance time in paragraph (i)(1) of this AD has been adjusted to accommodate airplanes with generators close to the 15-year life limit as of the effective date of the AD. This change is not more restrictive than what was proposed, and does not expand the

scope of the requirement as specified in the proposed AD.

Conclusion

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

Related Service Information

Collins Aerospace Service Information Letter (SIL) 117080–SIL–002, dated May 4, 2022, specifies procedures for replacing affected chemical oxygen generators.

Costs of Compliance

The FAA estimates that this AD affects 3,419 airplanes of U.S. registry. The FAA estimates the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection	4 work-hours × $85 per hour = $340.	$0	$340	$1,162,460.
Replacement	0.50 work-hour × $85 per hour = $43 per replacement cycle.	Up to $445	Up to $488 per replacement cycle.	$1,668,472 per replacement cycle.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

(2) Will not affect intrastate aviation in Alaska, and

(3) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

2023–13–12 The Boeing Company: Amendment 39–22497; Docket No. FAA–2022–1479; Project Identifier AD–2022–00703–T.

(a) Effective Date

This airworthiness directive (AD) is effective September 5, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to all The Boeing Company Model 737–100, 737–200, 737–200C, 737–300, 737–400, 737–500, 737–600, 737–700, 737–700C, 737–800, 737–900, 737–900ER, 757–200, 757–200PF, 757–200CB, 757–300, 767–200, 767–300, 767–300F, and 767–400ER series airplanes, certificated in any category.

(d) Subject

Air Transport Association (ATA) of America Code 35, Oxygen.

(e) Unsafe Condition

This AD was prompted by reports of premature aging of certain chemical oxygen generators. The FAA is issuing this AD to address this premature aging that resulted in the generators failing to activate, which could fail to deliver oxygen during an emergency, possibly resulting in injury to the airplane occupants.

(f) Compliance

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

(g) Oxygen Generator Part Number Inspection

Within 30 days after the effective date of this AD: Inspect passenger chemical oxygen generators having part numbers 117080–02, 117080–03, and 117080–04 to determine their date of manufacture. A review of airplane maintenance records is acceptable for the inspection, provided the date of manufacture can be conclusively determined by that review.

(h) Definition

For purposes of this AD, a serviceable unit is a passenger chemical oxygen generator that meets the condition specified in either paragraph (h)(1) or (2) of this AD.

(1) Part numbers 117080–02, 117080–03, and 117080–04, with a manufacturing date not older than 10 years.

(2) Approved part numbers other than 117080–02, 117080–03, and 117080–04, provided the generator has not exceeded the life limit established for that generator by the manufacturer.

(i) Oxygen Generator Replacement

For any passenger chemical oxygen generators having part numbers 117080–02, 117080–03, and 117080–04: At the applicable time specified in paragraph (i)(1) through (4) of this AD, replace the chemical oxygen generator with a serviceable unit, as defined in this AD. Thereafter, replace chemical oxygen generators having part numbers 117080–02, 117080–03, and 117080–04 with serviceable units, as defined in this AD,

before exceeding 10 years since date of manufacture.

Note 1 to paragraph (i): Additional guidance for replacing the affected passenger chemical oxygen generators can be found in Collins Aerospace Service Information Letter 117080–SIL–002, dated May 4, 2022, and approved maintenance procedures.

(1) After doing the inspection in paragraph (g) of this AD: If the passenger chemical oxygen generator has a date of manufacture in 2008 or earlier, replace before further flight or within 15 years since the date of manufacture, whichever occurs later.

(2) For passenger chemical oxygen generators that have a date of manufacture in 2009 or 2010: Replace within 12 months after the effective date of this AD.

(3) For passenger chemical oxygen generators that have a date of manufacture in 2011, 2012, or 2013: Replace within 24 months after the effective date of this AD.

(4) For passenger chemical oxygen generators that have a date of manufacture in 2014 or later: Replace before exceeding 10 years since the date of manufacture, or within 24 months after the effective date of this AD, whichever occurs later.

(j) Parts Installation Limitation

As of the effective date of this AD, no person may install a passenger chemical oxygen generator, unless the oxygen generator is a serviceable unit, as defined in this AD.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

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

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

(l) Related Information

(1) For more information about this AD, contact Nicole S. Tsang, Aviation Safety Engineer, FAA, 2200 South 216th St., Des Moines, WA 98198; phone: 206–231–3959; email: *nicole.s.tsang@faa.gov.*

(2) For Collins Aerospace service information identified in this AD that is not incorporated by reference, contact Collins Aerospace, 15701 West 95th Street, Lenexa, KS 66219; email *ISPublications@collins.com;* website *tpi.beaerospace.com/Authentication.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(m) Material Incorporated by Reference

None.

Issued on June 30, 2023.

Michael Linegang,

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

[FR Doc. 2023–16121 Filed 7–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2023–0601]

Drawbridge Operation Regulation: Atlantic Intracoastal Waterway; West Palm Beach, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations; request for comments.

SUMMARY: The Coast Guard is issuing a temporary deviation from the operating schedule that governs the Flagler Memorial Bridge, across Atlantic Intracoastal Waterway (AICW), mile 1021.8, at West Palm Beach, Florida. Palm Beach County and the communities surrounding the bridge have requested the Coast Guard consider placing additional weekday restrictions during peak traffic hours to assist with alleviating vehicle congestion. This deviation will test a change to the drawbridge operation schedule to determine whether a permanent change to the schedule is needed. The Coast Guard is seeking comments from the public regarding this deviation.

DATES: This deviation is effective from 12:01 a.m. on August 1, 2023, through 11:59 p.m. on January 22, 2024.

Comments and related material must reach the Coast Guard on or before September 29, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–2023–0601 using Federal Decision Making Portal at *https://www.regulations.gov.*

See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this test deviation, call or email If you have questions on this test deviation, call or email Ms. Jennifer Zercher, Bridge Management Specialist, Seventh Coast Guard District; telephone 305–415–6740, email *Jennifer.N.Zercher@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Background, Purpose and Legal Basis

The Flagler Memorial Bridge, across Atlantic Intracoastal Waterway (AICW), mile 1021.8, at West Palm Beach, Florida is a double-leaf bascule bridge with a 24-foot vertical clearance at mean high water in the closed position. The normal operating schedule is set forth in 33 CFR 117.261(u).

Palm Beach County and communities surrounding the bridge requested the Coast Guard consider allowing the drawbridge to remain closed to navigation during morning and evening peak traffic hours. The Coast Guard has determined that allowing extended daily closures along this portion of the AICW will not meet the reasonable needs of navigation. However, to assist Palm Beach County and communities surrounding the bridge with alleviating vehicle traffic in the area, the Coast Guard is issuing the following temporary deviation to test an alternate drawbridge operating schedule.

Under this temporary deviation, the Flagler Memorial Bridge will open on the quarter and three-quarter hour, except that Monday through Friday (except Federal holidays) from 7:30 to 9 a.m. and from 4 to 6 p.m., the draw need only open on the quarter hour.

The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

II. Public Participation and Request for Comments

We view public participation as essential and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this

temporary deviation. If you submit a comment, please include the docket number for this temporary deviation, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

Submitting comments. We encourage you to submit comments through the Federal Decision Making Portal at *https://www.regulations.gov.* To do so, go to *https://www.regulations.gov,* type USCG- 2023–0601 in the search box and click ''Search.'' Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using *https://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

View material in the docket. To view documents mentioned in this deviation as being available in the docket, find the docket as described in the previous paragraph, and then select ''Supporting & Related Material'' in the Document Type column. Public comments will also be placed in our online docket and can be viewed by following instructions on the *https://www.regulations.gov* Frequently Asked Questions web page. Also, if you go to the online docket and sign up for email alerts, you will be notified when comments, future actions or updates are posted to the docket.

We review all comments received, but we will only post comments that address the topic of this deviation. We may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

We accept anonymous comments. Comments we post to *https://www.regulations.gov* will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Dated: July 26, 2023.

Randall D. Overton,

Director, Bridge Administration, Seventh Coast Guard District.

[FR Doc. 2023–16152 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0614]

RIN 1625–AA00

Safety Zone; Fleet Week Maritime Festival, Pier 62, Elliot Bay, Seattle, Washington

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for navigable waters within a box encompassed by the points 47°36.719′ N, 122°21.099′ W; 47°36.682′ N, 122°21.149′ W; 47°36.504′ N, 122°20.723′ W; 47°36.469′ N, 122°20.773′ W located in Elliott Bay, Seattle, WA, from thirty minutes prior to the beginning through thirty minutes following the conclusion of the parade of ships. This action is necessary to promote safety on navigable waters. During the enforcement period, entry into, transit through, mooring, or anchoring within this zone is prohibited unless authorized by the Captain of the Port, Sector Puget Sound or a designated representative.

DATES: This temporary rule is effective from 11:30 a.m. until 2:30 p.m. on August 1, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0614 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

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

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable to publish an NPRM for this temporary rule because we must establish the safety zone by August 1, 2023, to protect the public.

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** because delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with the parade event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. Due to the Parade of Ships taking place near Pier 62, Elliott Bay, Seattle, WA, on August 1, 2023, there will be a safety concern for anyone within a box encompassed by the points 47°36.719′ N, 122°21.099′ W; 47°36.682′ N, 122°21.149′ W; 47°36.504′ N, 122°20.723′ W; 47°36.469′ N, 122°20.773′ W. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone associated with the Parade of Ships.

IV. Discussion of the Rule

This rule establishes a safety zone for this year's Parade of Ships, the Pass in Review of which will occur on Pier 62. The duration of the zone is intended to protect personnel, vessels, and the marine environment in these navigable waters near Pier 62. No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. The safety zone will be enforced from 11:30 a.m. until 2:30 p.m. on August 1, 2023.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based on the size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which will impact a small, designated area of Elliott Bay for 2 hours. Moreover, the Coast Guard will issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone, and the rule will allow vessel operators 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 will not have a significant economic impact on a substantial number of small entities.

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone lasting only 3 hours that will prohibit entry within 100 yards of Pier 62. It is categorically excluded from further review under paragraph L60a of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T13–0614 to read as follows:

§ 165.T13–0614 Safety Zone; Fleet Week Maritime Festival, Pier 62, Elliott Bay, Seattle, Washington.

(a) *Location.* The following area is a safety zone: All waters extending 100 yards from Pier 62, Elliott Bay, WA within a box encompassed by the points, 47°36.719′ N, 122°21.099′ W; 47°36.682′ N, 122°21.149′ W; 47°36.504′ N, 122°20.723′ W; 47°36.469′ N, 122°20.773′ W.

(b) *Regulations.* In accordance with the general regulations in 33 CFR part 165, subpart C, no vessel operator may enter, transit, moor, or anchor within this safety zone, except for vessels authorized by the Captain of the Port or

Designated Representative, thirty minutes prior to the beginning, during and thirty minutes following the conclusion of the Parade of Ships. For the purpose of this rule, the Parade of Ships includes both the pass and review of the ships near Pier 62 and the aerial demonstrations immediately following the pass and review. The Captain of the Port may be assisted by other federal, state, or local agencies as needed.

(c) *Authorization.* In order to transit through this safety zone, authorization must be granted by the Captain of the Port, Puget Sound, or their Designated Representative. All vessel operators desiring entry into this safety zone shall gain authorization by contacting either the on-scene U.S. Coast Guard patrol craft on VHF Ch 13 or Ch 16, or Coast Guard Sector Puget Sound Joint Harbor Operations Center (JHOC) via telephone at (206) 217–6002. Requests shall indicate the reason why movement within the safety zone is necessary and the vessel's arrival and/or departure facility name, pier and/or berth. Vessel operators granted permission to enter this safety zone will be escorted by the on-scene patrol until no longer within the safety zone.

(d) *Enforcement period.* This section will be enforced from 11:30 a.m. until 2:30 p.m. on August 1, 2023.

Dated: July 24, 2023.

M.A. McDonnell,

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

[FR Doc. 2023–16069 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0580]

RIN 1625–AA00

Safety Zone; Lake Erie, Cleveland, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for certain waters of Lake Erie. This action is necessary to provide for the safety of life on navigable waters near Cleveland, OH, during the Tri CLE Rock and Roll Run which will be held on August 11 and 12, 2023. This rule will prohibit persons and vessels from entering the safety zone unless authorized by the Captain of the Port Buffalo.

DATES: This rule is effective from 11:45 a.m. on August 11, 2023, through 12:15 p.m. on August 12, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0580 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 Jared Stevens, Waterways Management Division, MSU Cleveland, U.S. Coast Guard; telephone 216–937–0124, email *Jared.M.Stevens@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because insufficient time remains before the event to publish an NPRM and receive public comments prior to the event.

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 to wait for a comment period to run would be contrary to the public interest by inhibiting the Coast Guard's ability to protect participants in these navigable waters before, during, and after the swim portion of the Tri CLE Rock and Roll Run triathlon.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP Buffalo has determined a safety zone is needed to protect swimmers on August 11 and 12, 2023 who will be participating in the triathlon located in the North Coast Harbor in Cleveland, Ohio.

IV. Discussion of the Rule

This rule establishes a safety zone from 11:45 a.m. through 2:15 p.m. on August 11, 2023, and again from 4:45 a.m. through 12:15 p.m. on August 12, 2023. The safety zone will cover all navigable waters in the North Coast Harbor and into the East Basin Channel on Lake Erie in Cleveland, OH. The zone may require enforcement beyond the stated times in the event the triathlon runs into unforeseen delays. The boundaries of the safety zone will form a rectangle with the four corners of the polygon located in the following positions: (1) 41°30′41″ N, 081°42′01″ W; (2) 41°30′47″ N, 081°41′53″ W; (3) 41°30′32″ N, 081°41′39″ W; (4) 41°30′27″ N, 081°41′47″ W (NAD 83).

The COTP Buffalo has determined a safety zone is needed to protect participants before, during, and after the swim portion of the Tri CLE Rock and Roll Run triathlon. No vessel or person would be permitted to enter the safety zone without obtaining permission from the COTP, or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based the need to ensure the safety of participants in these navigable waters before, during, and after the swim portion of the Tri CLE Rock Roll Run triathlon.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone intended to ensure the safety of participants in these navigable waters before, during, and after the swim portion of the Tri CLE Rock Roll Run triathlon. It is categorically excluded from further review under paragraph L63(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0580 to read as follows:

§ 165.T09–0580 Safety Zone; Tri CLE Rock and Roll Run, Lake Erie, Cleveland, OH.

a. *Location.* Cleveland, OH. All U.S. waters of Lake Erie and Cleveland Harbor within a rectangle with the four corners of the polygon located in the following positions: (1) 41°30′41″ N, 081°42′01″ W; (2) 41°30′47″ N, 081°41′53″ W; (3) 41°30′32″ N, 081° 41′ 39″ W; (4) 41°30′27″ N, 081°41′47″ W (NAD 83).

b. *Enforcement Period.* This section will be enforced from 11:45 a.m. through 2:15 p.m. on August 11, 2023, and from 4:45 a.m. through 12:15 p.m. on August 12, 2023.

c. *Definitions. Official Patrol Vessel* 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 Sector Buffalo, (COTP) in the enforcement of the regulations in this section. *Participant* means all persons and vessels attending the event.

d. *Regulations.*

(1) The Coast Guard may patrol the event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM.''

(2) All persons and vessels not registered with the sponsor as participants or official patrol vessels are considered spectators. The ''official patrol vessels'' consist of any Coast Guard, state or local law enforcement and sponsor provided vessels designated or assigned by the COTP Sector Buffalo, to patrol the event.

(3) Spectator vessels desiring to transit the regulated area may do so only with prior approval of the Patrol Commander and when so directed by that officer and will be operated at a no wake speed in a manner which will not endanger participants in the event or any other craft.

(4) No spectator shall anchor, block, loiter, or impede the through transit of official patrol vessels in the regulated area during the effective dates and times, unless cleared for entry by or through an official patrol vessel.

(5) The Patrol Commander may forbid and control the movement of all vessels in the regulated area. When hailed or signaled by an official patrol vessel, a vessel shall come to an immediate stop and comply with the directions given. Failure to do so may result in expulsion from the area, citation for failure to comply, or both.

(6) Any spectator vessel may anchor outside the regulated areas specified in this chapter, but may not anchor in, block, or loiter in a navigable channel.

(7) The Patrol Commander may terminate the event or the operation of any vessel at any time it is deemed necessary for the protection of life or property.

(8) The Patrol Commander will terminate enforcement of the special regulations at the conclusion of the event.

Dated: July 25, 2023.

M.I. Kuperman,

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

[FR Doc. 2023–16153 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0490]

RIN 1625–AA00

Safety Zone; Mercury Powerboat Race; Sheboygan Harbor, Sheboygan, Wisconsin

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing two temporary safety zones in Lake Michigan for certain navigable waters in and around Sheboygan Harbor in Sheboygan, WI. The safety zones are needed to protect personnel, vessels, and the marine environment from potential hazards association from the Mercury Powerboat Race event. This rule will prohibit persons and vessels from entering the safety zones unless authorized by the Captain of the Port Lake Michigan or a designated representative.

DATES: This rule is effective from 8 a.m. on August 11 to 6:30 p.m. on August 13, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0490 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 proposed rulemaking, call or email Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7136, email *brianna.m.henry@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because insufficient time remains before the event to publish an NPRM and receive public comments prior to the event.

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 to wait for a comment period to run would be contrary to the public interest by inhibiting the Coast Guard's ability to protect personnel, vessels, and the marine environment in these navigable waters during the race events.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The COTP Lake Michigan has determined a safety zone is needed to protect the public from potential hazards association from the Mercury Powerboat Race event.

IV. Discussion of the Rule

The COTP is establishing two safety zones from 8:00 a.m. on August 11 to 6:30 p.m. on August 13, 2023. One of the safety zones will be located offshore of Sheboygan, WI and will cover all navigable waters within the offshore course located within the following coordinates: NW corner 43°44′54.32″ N 87°42′5.77″ W, NE corner 43°44′54.10″ N 87°41′3.21″ W, SW corner, 43°42′27.10″ N 87°42′10.11″ W, SE corner 43°42′26.73″ N 87°40′54.66″ W. The other safety zone will be in a triangular area within Sheboygan Harbor and will cover all navigable waters within the following coordinates: 43°44′56.76″ N 87°41′05.60″ W, 43°45′07.29″ N 87°41′51.07″ W, 43°44′57.24″ N 87°42′05.24″ W. The duration of the zones is intended to protect personnel, vessels, and the marine environment in these navigable waters during the race events. Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or a designated representative.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

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

This regulatory action determination is based the need to ensure the safety of public during the powerboat race event.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended,

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

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

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

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves establishment of a temporary safety zone intended to ensure the safety of participants in these navigable waters before, during, and after the swim portion of the Tri CLE Rock Roll Run triathlon. It is categorically excluded from further review under paragraph L63(b) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0490 to read as follows:

§ 165.T09–0490 Safety Zone; Mercury Powerboat Race; Sheboygan Harbor, Sheboygan, Wisconsin

(a) *Location.* All navigable waters within the offshore course located within the following coordinates: NW corner 43°44′54.32″ N 87°42′5.77″ W, NE corner 43°44′54.10″ N 87°41′3.21″ W, SW corner, 43°42′27.10″ N 87°42′10.11″ W, SE corner 43°42′26.73″ N 87°40′54.66″ W, and all navigable waters located in a triangular area within Sheboygan Harbor within the following coordinates: 43°44′56.76″, N 87°41′05.60″ W, 43°45′07.29″ N 87°41′51.07″ W, 43°44′57.24″ N 87°42′05.24″ W.

(b) *Enforcement Period.* 8 a.m. on August 11 to 6:30 p.m. on August 13, 2023

(c) *Regulations.*

(1) In accordance with the general regulations in § 165.23, entry, transiting, or anchoring within this safety zones are prohibited unless authorized by the Captain of the Port Lake Michigan (COTP) or a designated representative.

(2) These safety zones are closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) The ''designated representative'' of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and vessel operators desiring to enter or operate within the safety zones must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zones must comply

with all directions given to them by the COTP or an on-scene representative.

Dated: July 25, 2023.

Joseph B. Parker,

Captain, U.S. Coast Guard, Captain of the Port Lake Michigan.

[FR Doc. 2023–16165 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–04–P

LIBRARY OF CONGRESS

Copyright Office

37 CFR Parts 222, 224, 225, 233, 234 and 235

[Docket No. 2022–6]

Copyright Claims Board: District Court Referrals; Proof of Service Forms; Default Proceedings; Law Student Representation

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final rule.

SUMMARY: Pursuant to the Copyright Alternative in Small-Claims Enforcement Act, the U.S. Copyright Office is adopting as final a December 19, 2022 interim rule allowing the Copyright Claims Board to modify or suspend certain rules when a claim is referred by a district court and, in cases that are first filed before the Copyright Claims Board, accept alternative proof of service forms. The interim rule also clarified the rules governing default proceedings and law student representation, and made certain technical corrections.

DATES: Effective August 30, 2023.

FOR FURTHER INFORMATION CONTACT: Rhea Efthimiadis, Assistant to the General Counsel, by email at *meft@copyright.gov* or telephone at (202) 707–8350.

SUPPLEMENTARY INFORMATION: The Copyright Alternative in Small-Claims Enforcement Act of 2020 (the ''CASE Act'') [1] directed the Copyright Office to establish the Copyright Claims Board (the ''CCB''), an alternative and voluntary forum for parties seeking to resolve certain copyright-related disputes that have a total monetary value of $30,000 or less.

After publishing a notification of inquiry (''NOI'') seeking public input on the CCB's operations and procedures in early 2021,[2] the Office published multiple notices of proposed rulemaking (''NPRMs'') addressing various aspects of CCB proceedings.[3] The Office then published final rules after receiving and considering comments from the public.[4] On June 16, 2022, the CCB began receiving claims.

On December 19, 2022, the Office published and sought comment on an interim rule that clarified the rules governing representation by law students of parties before the CCB, added a rule to address district court referrals, and amended the rules governing proof of service forms and default proceedings.[5] Specifically, the interim rule clarified that law student representatives must qualify under the laws, court rules, or bar rules of the jurisdiction that allows, authorizes, or permits them to practice law. This clarification was intended to avoid any implication in the prior rule that law students must undergo a formal certification process. The interim rule also clarified that the CCB's regulations only govern law students who make a formal appearance in CCB proceedings, rather than those who provide legal assistance to parties in other capacities.

The interim rule also set forth intake procedures for cases referred to the CCB from district courts and gave the CCB authority to adjust or suspend certain rules that would otherwise apply if doing so would be in the interests of efficiently resolving the dispute. The interim rule excluded district court referrals from the limits on the number of proceedings a claim, attorney, or law firm may file with the CCB, and did not require a claimant to pay a filing fee for such a proceeding.

Further, the interim rule made clear that claimants may file either the proof of service form provided on the CCB's website or an alternative proof of service form that contains all of the information required by the CCB-provided form. The interim rule also clarified that parties are not limited to materials exchanged during discovery when presenting evidence in support of a default. Finally, the interim rule included updated cross-references and added references to ''counterclaims'' where the rule previously only referred to ''claims.''

The Office received one comment on the interim rule from the Copyright Alliance, concerning the decision not to require claimants to pay a fee for proceedings referred to the CCB by a district court.[6] The Copyright Alliance indicated that it had no objections to this approach, but recommended that ''the Office monitor the number of cases referred from district court and re-evaluate the impact of this rule'' to make sure that costs are not passed to other claimants and that the CCB's budget or resources are not negatively impacted, in the event that district court referrals become a significant portion of the CCB's caseload.[7] If that occurs, the Copyright Alliance suggested that the Office ''includ[e] an amount sufficient to fund these cases in its annual appropriations funding request from Congress'' or, if the Office opts to impose a fee in the future, that it ''divid[e] that fee equally among all of the claimants and respondents that would be party to the case.'' [8]

The Office appreciates these comments and will take them under advisement moving forward. Because the Office did not receive any comments recommending changes to the proposed rule at this time, the Office adopts the interim rule as final.

List of Subjects in 37 CFR Parts 222, 224, 225, 233, 234, and 235

Claims, Copyright.

Final Regulations

PART 222—PROCEEDINGS

PART 224—REVIEW OF CLAIMS BY OFFICERS AND ATTORNEYS

PART 225—DISCOVERY

PART 233—LIMITATION ON PROCEEDINGS

PART 234—LAW STUDENT REPRESENTATIVES

PART 235—DISTRICT COURT REFERRALS

■ For the reasons stated in the preamble, the U.S. Copyright Office adopts the interim rule amending 37 CFR parts 222, 224, 225, 233, 234, and 235, which was published at 87 FR 77518 on December 19, 2022, as final without change.

[1] Public Law 116–260, sec. 212, 134 Stat. 1182, 2176 (2020).

[2] 86 FR 16156 (Mar. 26, 2021).

[3] *See, e.g.,* 86 FR 74394 (Dec. 30, 2021); 86 FR 53897 (Sept. 29, 2021); 86 FR 69890 (Dec. 8, 2021).

[4] 87 FR 20707 (Apr. 8, 2022) (law student representation final rule); 87 FR 12861 (Mar. 8, 2022) (initial proceedings partial final rule); 87 FR 16989 (Mar. 25, 2022) (initial proceedings final rule); 87 FR 24056 (Apr. 22, 2022) (initial proceedings correction); 87 FR 30060 (May 17, 2022) (active proceedings final rule); 87 FR 36060 (June 15, 2022) (active proceedings correction).

[5] 87 FR 77518 (Dec. 19, 2022).

[6] Copyright Alliance Interim Rule Comments at 1.

[7] Copyright Alliance Interim Rule Comments at 1–2.

[8] Copyright Alliance Interim Rule Comments at 2.

Dated: July 19, 2023.

Shira Perlmutter,

Register of Copyrights and Director of the U.S. Copyright Office.

Approved by:

Carla D. Hayden,

Librarian of Congress.

[FR Doc. 2023–15941 Filed 7–28–23; 8:45 am]

BILLING CODE 1410–30–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 97

[EPA–HQ–OAR–2021–0668; FRL–8670.2–03–OAR]

Federal "Good Neighbor Plan" for the 2015 Ozone National Ambient Air Quality Standards; Response to Judicial Stays of SIP Disapproval Action for Certain States

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final rule; request for comment.

SUMMARY: The Environmental Protection Agency (EPA) is taking interim final action to stay, for emissions sources in Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas only, the effectiveness of the federal implementation plan (FIP) requirements established to address the obligations of these and other states to mitigate interstate air pollution with respect to the 2015 national ambient air quality standards (NAAQS) for ozone (the Good Neighbor Plan). The EPA is also revising certain other regulations to ensure that sources in these states will continue to be subject to previously established requirements to mitigate interstate air pollution with respect to other ozone NAAQS while the Good Neighbor Plan's requirements are stayed. These revisions will also ensure that the stay is limited to requirements for which the EPA does not currently have authority to implement a FIP pending judicial review. The stay and the associated revisions to other regulations are being issued in response to judicial orders that partially stay, pending judicial review, a separate, earlier EPA action which disapproved certain state implementation plan (SIP) revisions submitted by these and other states. Finally, for states for which the Good Neighbor Plan's requirements are not being stayed, the EPA is revising three near-term deadlines that are incorrect as published in the Good Neighbor Plan.

DATES: This interim final rule is effective on August 4, 2023. Comments on this rule must be received on or before August 30, 2023.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2021–0668, by any of the following methods:

- *Federal eRulemaking portal: https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand delivery or courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except federal holidays).

Comments received may be posted without change to *https://www.regulations.gov,* including any personal information provided. For detailed instructions on sending comments, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: David Lifland, Clean Air Markets Division, Office of Atmospheric Protection, Office of Air and Radiation, U.S. Environmental Protection Agency, Mail Code 6204A, 1200 Pennsylvania Avenue NW, Washington, DC 20460; telephone: 202–343–9151; email: *lifland.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General

A. Public Participation

Submit your written comments, identified by Docket ID No. EPA–HQ–OAR–2021–0668, at *https://www.regulations.gov* (our preferred method), or by the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit to the EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

B. Potentially Affected Entities

This action revises on an interim basis the Good Neighbor Plan, which applies to electricity generating units (EGUs) and non-EGU industrial sources. This action also revises other allowance trading program regulations that apply to EGUs but not to non-EGU industrial sources. The affected emissions sources are generally in the following industry groups:

Industry group	North American Industry Classification System (NAICS) code
Fossil Fuel Electric Power Generation	221112
Pipeline Transportation of Natural Gas	4862
Cement and Concrete Product Manufacturing	3273
Iron and Steel Mills and Ferroalloy Manufacturing	3311
Glass and Glass Product Manufacturing	3272
Basic Chemical Manufacturing	3251
Petroleum and Coal Products Manufacturing	3241
Pulp, Paper, and Paperboard Mills	3221
Metal Ore Mining	2122
Solid Waste Combustors and Incinerators	562213

The Good Neighbor Plan applies to emissions sources in Alabama, Arkansas, California, Illinois, Indiana, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Nevada, New Jersey, New York, Ohio, Oklahoma, Pennsylvania, Texas, Utah, Virginia, West Virginia, and Wisconsin. The portions of this action staying the Good Neighbor Plan's requirements and revising other allowance trading program regulations apply to sources in Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas. The portions of this action revising certain near-term deadlines under the Good Neighbor Plan apply to emissions sources in the other listed states, for which the Good Neighbor Plan's requirements are not being stayed.

The information provided in this section on potentially affected entities is not intended to be exhaustive. If you have questions regarding the applicability of this action to a

particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

C. Statutory Authority

Statutory authority to issue the amendments finalized in this action is provided by the same Clean Air Act (CAA) provisions that provided authority to issue the regulations being amended: CAA section 110(a) and (c), 42 U.S.C. 7410(a) and (c) (SIP and FIP requirements, including requirements for mitigation of interstate air pollution), and CAA section 301, 42 U.S.C. 7601 (general rulemaking authority). Statutory authority for the rulemaking procedures followed in this action is provided by Administrative Procedure Act (APA) section 553, 5 U.S.C. 553.

II. Regulatory Revisions

A. Response to Stay Orders

1. Background and Summary

CAA section 110(a)(2)(D)(i)(I), also known as the ''good neighbor'' provision, requires each state's SIP to include provisions sufficient to ''prohibit[ ], consistent with the provisions of this subchapter, any source or other type of emissions activity within the State from emitting any air pollutant in amounts which will—(I) contribute significantly to nonattainment in, or interfere with maintenance by, any other State with respect to any [NAAQS].'' The EPA often refers to the emissions reduction requirements under this provision as ''good neighbor obligations'' and submissions addressing these requirements as ''good neighbor SIPs.''

CAA section 110(c)(1) requires the EPA Administrator to promulgate a FIP at any time within two years after the Administrator: (i) finds that a state has failed to make a required SIP submission; (ii) finds a SIP submission to be incomplete pursuant to CAA section 110(k)(1)(C); or (iii) disapproves a SIP submission. This obligation applies unless the state corrects the deficiency through a SIP revision that the Administrator approves before the FIP is promulgated.

On February 13, 2023, the EPA published a final action fully or partially disapproving good neighbor SIPs submitted by 21 states with respect to the 2015 ozone NAAQS (the SIP Disapproval action).[1] Consistent with the requirements of CAA section 110(c)(1), following the SIP Disapproval action, on March 15, 2023, the EPA Administrator signed a separate final action promulgating a FIP, which is referred to here as the ''Good Neighbor Plan'' or the ''Rule.''[2] The Good Neighbor Plan requires EGUs and non-EGU industrial sources in the 21 states whose good neighbor SIPs the EPA had disapproved in the SIP Disapproval action (as well as two other states for which the EPA had previously made findings of failure to submit good neighbor SIPs) to reduce their emissions of nitrogen oxides (NO_X) during the May-September ''ozone season'' to address the states' good neighbor obligations with respect to the 2015 ozone NAAQS.[3] The Good Neighbor Plan was published in the **Federal Register** on June 5, 2023, and its requirements will be phased in over several years starting on the Rule's August 4, 2023, effective date.

To implement the required emissions reductions from EGUs, the Good Neighbor Plan uses an emissions allowance trading program. The EPA has previously established three successive allowance trading programs for EGUs' seasonal NO_X emissions to address states' good neighbor obligations with respect to the 1997 and 2008 ozone NAAQS—referred to here as the CSAPR NO_X Ozone Season ''Group 1,'' ''Group 2,'' and ''Group 3'' trading programs—in the Cross-State Air Pollution Rule (CSAPR),[4] the CSAPR Update,[5] and the Revised CSAPR Update,[6] respectively. The Good Neighbor Plan does not establish a new emissions trading program, but instead modifies the Group 3 trading program initially established in the Revised CSAPR Update and expands the program to apply to EGUs in the additional states included in the Good Neighbor Plan.

In each of the successive rulemakings to address good neighbor obligations with respect to an ozone NAAQS, the EPA has coordinated compliance requirements by allowing the participation of a state's EGUs in the most recent seasonal NO_X trading program to also satisfy any requirements to participate in a previous seasonal NO_X trading program established to address the state's good neighbor obligations with respect to a less protective NAAQS.[7] Because of the EPA's coordination efforts, for 19 of the states covered by the Good Neighbor Plan as signed, including Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas, participation of the state's EGUs in the Group 3 trading program not only serves as the mechanism for partially addressing the states' good neighbor obligations with respect to the 2015 ozone NAAQS, but also serves as the mechanism for addressing the states' good neighbor obligations with respect to the 2008 ozone NAAQS.[8] For eight of the states, including Arkansas, Kentucky, Louisiana, Mississippi, and Missouri, participation of the states' EGUs in the Group 3 trading program serves as the mechanism for addressing the states' good neighbor obligations with respect to the 1997 ozone NAAQS as well.[9]

Petitioners challenging the SIP Disapproval action have filed motions in several courts for partial stays of that action with respect to the SIPs submitted by particular states. Subsequent to the Good Neighbor Plan's signature date, courts have granted some of these motions. On May 1 and June 8, 2023, the U.S. Court of Appeals for the Fifth Circuit issued orders staying the SIP Disapproval action with respect to Louisiana, Mississippi, and Texas pending judicial review on the merits.[10] On May 25 and 26, 2023, the U.S. Court of Appeals for the Eighth Circuit issued orders staying the SIP Disapproval action with respect to Arkansas and Missouri pending judicial review on the merits.[11] On May 31, 2023, the U.S. Court of Appeals for the Sixth Circuit issued an order administratively staying the SIP Disapproval action with respect

[1] Air Plan Disapprovals; Interstate Transport of Air Pollution for the 2015 8-Hour Ozone National Ambient Air Quality Standards, 88 FR 9336 (February 13, 2023).

[2] Federal ''Good Neighbor Plan'' for the 2015 Ozone National Ambient Air Quality Standards, 88 FR 36654 (June 5, 2023).

[3] *See generally id.* The Good Neighbor Plan's requirements for EGUs apply in 22 of the 23 covered states, while the requirements for non-EGU industrial sources apply in 20 of the 23 covered states.

[4] Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals, 76 FR 48208 (August 8, 2011). CSAPR addressed states' good neighbor obligations with respect to the 1997 ozone NAAQS, as well as the 1997 and 2006 NAAQS for fine particulate matter.

[5] Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS, 81 FR 74504 (October 26, 2016). The CSAPR Update addressed states' good neighbor obligations with respect to the 2008 ozone NAAQS.

[6] Revised Cross-State Air Pollution Rule Update for the 2008 Ozone NAAQS, 86 FR 23054 (April 30, 2021). The Revised CSAPR Update readdressed states' good neighbor obligations with respect to the 2008 ozone NAAQS in response to the remand of the CSAPR Update in *Wisconsin* v. *EPA,* 938 F.3d 303 (D.C. Cir. 2019).

[7] *See, e.g.,* 81 FR 74509; 86 FR 23122.

[8] *See* 88 FR 36844.

[9] *See id.*

[10] Order, *Texas* v. *EPA,* No. 23–60069 (5th Cir. May 1, 2023); Order, *Texas* v. *EPA,* No. 23–60069 (5th Cir. June 8, 2023). The orders are available in the docket.

[11] Order, *Arkansas* v. *EPA,* No. 23–1320 (8th Cir. May 25, 2023); Order, *Missouri* v. *EPA,* No. 23–1719 (8th Cir. May 26, 2023); Order, *Union Electric Co.* v. *EPA,* No. 23–1751 (8th Cir. May 26, 2023). The orders are available in the docket.

to Kentucky pending review of Kentucky's stay motion.[12]

The EPA's authority under CAA section 110(c)(1) to establish the Good Neighbor Plan's FIP requirements for the sources in a given state is triggered by either the EPA's disapproval of the state's good neighbor SIP with respect to the 2015 ozone NAAQS or the EPA's finding of the state's failure to submit such a SIP. Accordingly, as a result of the orders partially staying the SIP Disapproval action, the EPA must act to ensure that the Good Neighbor Plan's requirements that were issued to address good neighbor obligations with respect to the 2015 ozone NAAQS and that apply to either EGUs or non-EGU industrial sources in each of the states for which a stay order has been issued will not take effect while the stay of the SIP Disapproval action as to that state remains in place. To ensure full compliance with the stay orders, the EPA is also staying these requirements for sources in Indian country located within the borders of a state covered by a stay order, including areas of Indian country not subject to the state's SIP authority.[13] However, as noted earlier in this section, the Group 3 trading program is also the mechanism to implement requirements previously established for EGUs in most of the covered states to address the states' good neighbor obligations with respect to the 2008 ozone NAAQS and, in some cases, the 1997 ozone NAAQS. The SIP Disapproval action was not a basis for the authority relied on by the EPA in the previous rulemakings to establish emissions reduction requirements with respect to the 2008 or 1997 ozone NAAQS, and the stay orders do not affect these pre-existing requirements. The EPA's authority for the rulemakings addressing the 2008 and 1997 ozone NAAQS remains in place. Implementing the stay orders therefore requires the EPA not only to stay the new requirements established for EGUs and non-EGU industrial sources in the Good Neighbor Plan to address their states' good neighbor obligations with respect to the 2015 ozone NAAQS, but also to preserve status quo requirements established in previous rulemakings to address their states' good neighbor obligations with respect to the 2008 and 1997 ozone NAAQS.

Thus, the EPA in this action is revising the Good Neighbor Plan FIP requirements and the regulations for the Group 2 trading program to require the EGUs in each state covered by a stay order for the SIP Disapproval action to participate in the Group 2 trading program instead of the Group 3 trading program while the stay for that state remains in place. A small number of conforming revisions are also being made to the regulations for the Group 1 and Group 3 trading programs. Together, the revisions preserve the status quo by making the trading program requirements that will apply to the EGUs in each state for which the SIP Disapproval action has been stayed substantively identical to the trading program requirements that would have applied to the EGUs in that state if the state had not been covered by the Good Neighbor Plan. The revisions to the trading program regulations are summarized in the remainder of this section and are discussed in detail in section II.A.2 of this document.[14]

First, for EGUs in Arkansas, Mississippi, Missouri, and Texas, which before the Good Neighbor Plan were covered by the Group 2 trading program as promulgated in the CSAPR Update rather than the Group 3 trading program, the revisions in this action restore the state emissions budgets, unit-level allowance allocation provisions, and banked allowance holdings that would have been in effect for the EGUs in these states under the Group 2 trading program in the absence of the Good Neighbor Plan.

Second, for EGUs in Kentucky and Louisiana, which before the Good Neighbor Plan were already covered by the Group 3 trading program as promulgated in the Revised CSAPR Update, the revisions in this action modify the Group 2 and Group 3 trading program regulations so as to establish under the Group 2 trading program the state emissions budgets, unit-level allowance allocation provisions, and banked allowance holdings that would have been in effect for the EGUs in these states under the Group 3 trading program in the absence of the Good Neighbor Plan.

Finally, for EGUs in all states that will now be covered by the Group 2 trading program, the revisions in this action establish two non-interchangeable subtypes of Group 2 allowances: CSAPR NO_X Ozone Season Original Group 2 allowances and CSAPR NO_X Ozone Season Expanded Group 2 allowances.[15] EGUs in Arkansas, Mississippi, Missouri, and Texas, which would have been covered by the Group 2 trading program in the absence of the Good Neighbor Plan, will use Original Group 2 allowances for compliance (as will EGUs in Iowa, Kansas, and Tennessee, which are not covered by the Good Neighbor Plan and remain in the Group 2 trading program). EGUs in Kentucky and Louisiana, which would have been covered by the Group 3 trading program in the absence of the Good Neighbor Plan, will use Expanded Group 2 allowances for compliance. The requirements to use different subtypes of Group 2 allowances will preserve the status quo distinction between these two sets of EGUs that already existed before the Good Neighbor Plan and that continues to exist with the stay of the Good Neighbor Plan as to these states, because the allowances that EGUs in Kentucky and Louisiana have used for compliance under the Group 3 trading program as promulgated in the Revised CSAPR Update are not interchangeable with the allowances that EGUs in the other states have used for compliance under the Group 2 trading program.

The amendments to the regulatory requirements for EGUs and non-EGU industrial sources that the EPA is finalizing in this action in response to the stay orders are being made on an interim basis and will remain in place while the judicial proceedings in which the stay orders were issued remain pending. After the courts have reached final determinations on the merits in those proceedings, the EPA will take further action consistent with the final determinations. At the time of this rulemaking, the EPA cannot predict how the Agency's future action may affect the amendments being finalized in this action.

2. Specific Regulatory Revisions

The regulatory revisions to 40 CFR part 52 that are being adopted in this action to implement the orders staying the SIP Disapproval action for non-EGU industrial sources in Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas and Indian country

[12] Order, *Kentucky* v. *EPA,* No. 23–3216 (6th Cir. May 31, 2023), available in the docket.

[13] For sources in areas of Indian country not subject to the SIP authority of the states within whose borders the areas of Indian country are located, the EPA issued the Good Neighbor Plan's requirements not under authority of CAA section 110(c)(1) but under authority of CAA section 301(d)(4). *See* 88 FR 36690–92. However, because the EPA exercised its authority under CAA section 301(d)(4) only with respect to areas of Indian country within the borders of states for which requirements were being issued under CAA section 110(c)(1), *id.* at 36692, these areas of Indian country are indirectly implicated by the orders partially staying the SIP Disapproval action for the respective states.

[14] The EPA has included documents in the docket that show all the regulatory revisions being adopted in this action in redline-strikeout format.

[15] The non-interchangeability will be automatically enforced through the use of different codes for the two subtypes of Group 2 allowances in the EPA's Allowance Management System, where all allowance allocations, transfers, and deductions under the Group 2 trading program are recorded.

within the borders of those states include the addition of text at § 52.40(c)(4) to stay the effectiveness of the Good Neighbor Plan's requirements for non-EGU industrial sources at §§ 52.41 through 52.46 and the remainder of § 52.40 for states covered by stay orders and the addition of parallel text in the state-specific subparts of part 52 for each of the states.[16]

The regulatory revisions to 40 CFR parts 52 and 97 that are being adopted in this action to implement the orders staying the SIP Disapproval action for EGUs in Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas and Indian country within the borders of those states while ensuring continued implementation of requirements established to address good neighbor obligations under rules promulgated before the Good Neighbor Plan include the following:

- The addition of text at § 52.38(b)(2)(iii)(D) to stay the effectiveness of the Good Neighbor Plan's requirements at § 52.38(b)(2)(iii)(A) and (B) for EGUs to participate in the enhanced Group 3 trading program for control periods after 2022 for states covered by stay orders, the addition of text at § 52.38(b)(2)(ii)(D) to require those EGUs to participate in the Group 2 trading program while that stay remains in place, and the addition of parallel text in the state-specific subparts of part 52 for each of the states.[17]
- The revision of text at § 52.38(b)(16)(ii)(B) to provide for continued administration by the EPA after 2022, for states covered by stay orders, of state Group 2 trading programs integrated with the federal Group 2 trading program under approved SIP revisions.[18]
- The revision and addition of text at § 97.802 to define ''Original'' and ''Expanded'' subtypes of CSAPR NO_X Ozone Season Group 2 allowances, with conforming revisions and additions at §§ 97.502, 97.1002, 97.811(d) and (e), 97.821(e), 97.526(d) and (e), 97.826(d) through (f), and 52.38(b)(14).
- The revision of text at §§ 97.806(c), 97.824(a) and (d), and 97.825(a) to provide for EGUs in states covered by stay orders and covered by the Group 3 trading program before 2023 to use Expanded Group 2 allowances for compliance and for EGUs in other states covered by the Group 2 trading program to use Original Group 2 allowances for compliance, with conforming revisions at § 52.38(b)(14).
- The revision of text at § 97.810(a) and (b) to provide EGUs in states covered by stay orders the same amounts for state emissions budgets, new unit set-asides, Indian country new unit set-asides, and variability limits that would have applied under the Group 2 trading program or the Group 3 trading program, as applicable for the state, in the absence of the Good Neighbor Plan.
- The revision of text at § 97.811(a)(2) and § 97.821(e) to provide EGUs in states covered by stay orders the same unit-level allocation and recordation provisions that would have applied under the Group 2 trading program or the Group 3 trading program, as applicable for the state, in the absence of the Good Neighbor Plan.[19]
- The revision of text at §§ 97.830(b)(1) and 97.834(d)(2)(i) to provide EGUs in states that were covered by the Group 3 trading program before 2023 the same deadlines for commencement of monitoring and reporting activities that would have applied in the absence of the Good Neighbor Plan.
- The addition of text at § 97.1026(e) to provide for the conversion of banked 2021–2022 Group 3 allowances held by EGUs in states that that were covered by the Group 3 trading program before 2023 into Expanded Group 2 allowances, with conforming revisions at §§ 97.502, 97.802, 97.1002, 97.824(c), and 52.38(b)(14).
- The revision of text at §§ 97.811(e)(1) and 97.826(e)(1) to exclude EGUs in states covered by stay orders from the Good Neighbor Plan's provisions converting banked 2017–2022 Original Group 2 allowances into Group 3 allowances and recalling previously allocated 2023–2024 Original Group 2 allowances.
- The revision of text at §§ 97.816(c), 97.818(f), and 97.820(c)(1)(iv), (c)(2)(iv), and (c)(5)(vi) to include the transition of states from the Group 3 trading program to the Group 2 trading program in the provisions that allow the EPA to treat certain certifications, applications, and notices of delegation as valid despite the use of terminology intended for use under a different trading program.
- The revision of text at §§ 97.526(e) and 97.826(f) and the addition of text at § 97.1026(f) to include the transition of states from the Group 3 trading program to the Group 2 trading program in the provisions that specify when and how an EGU in a state that has moved between trading programs may use allowances from a later trading program to meet surrender requirements for past control periods under a previous trading program, with conforming revisions at § 52.38(b)(14).
- The revision of text at § 97.526(d)(2)(ii) and 97.826(d)(3) to include the conversion of Group 3 allowances to Expanded Group 2 allowances in the provisions that address future conversions of allowances that were allocated for past control periods under a given trading program to an EGU in a state no longer covered by that trading program, where the allowances would have been included in a previous conversion to a different type of allowances if the allocations had been recorded before the previous conversion took place.

B. Deadline Corrections

In addition to the regulatory revisions described in section II.A of this document that are being made on an interim basis in response to judicial stay orders, in this action the EPA is also permanently revising three near-term deadlines that are incorrect in the Good Neighbor Plan as published in the **Federal Register**. Unlike the revisions described in section II.A of this document, these revisions apply to emissions sources in the states whose coverage under the Good Neighbor Plan is not affected by a stay order.

The first deadline correction concerns a quarterly reporting deadline applicable to EGUs in states that were already covered by the Group 2 trading program or the Group 3 trading program before the 2023 ozone season. As explained in the Good Neighbor Plan preamble, these EGUs will participate in the revised Group 3 trading program for the entire 2023 ozone season, subject to transitional provisions ensuring that the only substantive new regulatory

[16] *See* §§ 52.184(b)(2) (Arkansas), 52.940(c)(2) (Kentucky), 52.984(e)(2) (Louisiana), 52.1284(b)(2) (Mississippi), 52.1326(c)(2) (Missouri), and 52.2283(e)(2) (Texas).

[17] *See* §§ 52.184(a)(6) (Arkansas), 52.940(b)(6) (Kentucky), 52.984(d)(6) (Louisiana), 52.1284(a)(6) (Mississippi), 52.1326(b)(6) (Missouri), and 52.2283(d)(6) (Texas).

[18] This revision ensures that Missouri's good neighbor obligations with respect to the 2008 and 1997 NAAQS can continue to be met through the participation of the state's EGUs in the state Group 2 trading program adopted by the state and included in the SIP revision that was approved by the EPA at 84 FR 66316 (December 4, 2019).

[19] For sources in states that were not covered by the Group 3 trading program before the Good Neighbor Plan, the applicable notice of data availability (NODA) referenced in revised § 97.811(a)(2)(i) as identifying the unit-level allocations of Original Group 2 allowances to existing units will be the NODA published at 81 FR 67190 (September 30, 2016) to implement the CSAPR Update. For sources in states that were covered by the Group 3 trading program before the Good Neighbor Plan, the applicable NODA referenced in revised § 97.811(a)(2)(ii) as identifying the unit-level allocations of Expanded Group 2 allowances to existing units will be the NODA published at 86 FR 26719 (May 17, 2021) to implement the Revised CSAPR Update.

requirements in 2023—specifically, the emissions control stringencies reflected in the revised Group 3 trading program's state emissions budgets and assurance levels—will take effect only after the Rule's effective date.[20] The Group 3 trading program's deadline for EGUs to submit quarterly reports of emissions and operating data for the first two months of the May–September ozone season in 2023 would normally have been July 31, 2023 (the first business day at least 30 days after the end of the second calendar quarter), but the timing of publication in the **Federal Register** caused the Good Neighbor Plan's effective date to fall four days after this date, on August 4, 2023. Accordingly, the EPA is extending the deadline in 40 CFR 97.1034(d)(3) by which EGUs subject to the Group 3 trading program must submit quarterly reports for this calendar quarter to August 4, 2023.[21] Further, because the quarterly reports required under the Group 3 trading program are consolidated with the quarterly reports required under several other EPA programs, the EPA is also amending 40 CFR 97.1034(d)(4) to similarly extend these EGUs' reporting deadlines under the other programs.

The second deadline correction concerns a quarterly reporting deadline applicable to EGUs in states that were not already covered by the Group 2 trading program or the Group 3 trading program before the 2023 ozone season. EGUs in these states will begin to participate in the Group 3 trading program as of the Good Neighbor Plan's effective date, and the regulations as published in the Rule correctly provide that most of these EGUs will be subject to the program's monitoring and reporting requirements for emissions occurring on and after August 4, 2023.[22] However, a separate regulatory provision incorrectly identifies the ending date of the first calendar quarter for which these EGUs must submit quarterly reports under the Group 3 trading program as June 30, 2023. The EPA is amending 40 CFR 97.1034(d)(2)(i)(C) to indicate the correct quarterly ending date of September 30, 2023. The deadline for EGUs to submit quarterly reports for this calendar quarter will be October 30, 2023.

The third deadline correction concerns a deadline for submission of initial notifications applicable to furnaces in the Glass and Glass Product Manufacturing industry that are subject to requirements under the Good Neighbor Plan. Because of a typographical error in the document submitted for publication in the **Federal Register**,the Rule as published incorrectly specifies a submission deadline of June 23, 2023 (the first business day at least 18 days after the Rule's publication date). The EPA is amending 40 CFR 52.44(j)(2) to specify the intended submission deadline of December 4, 2023 (the first business day at least *180* days after the Rule's publication date).

III. Rulemaking Procedures and Findings of Good Cause

As noted in section I.C of this document, the EPA's authority for the rulemaking procedures followed in this action is provided by APA section 553.[23] In general, an agency issuing a rule under the procedures in APA section 553 must provide prior notice and an opportunity for public comment, but APA section 553(b)(B) includes an exemption from notice-and-comment requirements ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.'' This action is being issued as an interim final rule without prior notice or opportunity for public comment because the EPA finds that the APA ''good cause'' exemption from notice-and-comment requirements applies here.

The EPA finds good cause to forgo notice-and-comment procedures because such procedures are both impracticable and unnecessary for this action. First, following notice-and-comment procedures is impracticable for the portions of this action responding to the stay orders because such procedures would require more time than is available. The earliest stay order to which the EPA must respond in this action was issued on May 1, 2023, just over three months before the Good Neighbor Plan's upcoming effective date on August 4, 2023, which is the date by which this action responding to the stay order must be effective. The most recent of the subsequent stay orders to which the EPA's action must also respond was issued less than two months before the Rule's upcoming effective date. The EPA does not consider even the maximum three-month period sufficient time in which to conduct a notice-and-comment rulemaking encompassing the time to, at a minimum, evaluate possible actions for responding to the stay orders, prepare and publish a proposal describing the action identified through that evaluation, wait for comments on the proposal, review the comments received, and prepare and publish a final rule and response to comments. It is not possible for all of these steps to be completed within a three-month period for this action.

Second, following notice-and-comment procedures is unnecessary for this action. With respect to the portions of this action that respond to the stay orders, the EPA has no discretion as to the regulatory revisions that stay the effectiveness of the Good Neighbor Plan's requirements for sources in the states covered by stay orders. While some superficial discretion exists concerning the specific design of the regulatory revisions that provide an alternate mechanism for EGUs in states covered by the stay orders to continue to address the states' good neighbor obligations with respect to the 2008 and 1997 NAAQS, no discretion exists as to the function of that design, which is to maintain the status quo by implementing requirements that are substantively identical to the pre-existing requirements that would have continued to apply in the absence of the Good Neighbor Plan. The EPA's design for the regulatory revisions in this action accomplishes this function. Taking comment on the portions of the action that respond to the stay orders so as to allow the public to advocate for not staying the Good Neighbor Plan's requirements, not adopting regulatory

[20] *See* 88 FR 36775–76; 88 FR 36811–13.

[21] All the EGUs that are required under the Good Neighbor Plan to submit quarterly reports for the second calendar quarter of 2023 already participate in either the Group 2 trading program or the Group 3 trading program and therefore have already installed and certified the necessary monitoring systems. The data elements of the quarterly reports that these EGUs are required to submit under the Group 3 trading program for their ozone season emissions in 2023 are identical to the data elements of the quarterly reports that the EGUs were required to submit under the Group 2 trading program or Group 3 trading program for their ozone season emissions in 2022 and previous years.

[22] *See* 40 CFR 97.1030(b)(1)(iii). Most EGUs covered under the Good Neighbor Plan that do not already participate in the Group 2 trading program or the Group 3 trading program are already subject to closely related monitoring and reporting requirements under other EPA programs and consequently have already installed and certified the monitoring systems necessary to monitor and report under the Group 3 trading program. For the small number of EGUs in these states that have not already been required to install and certify the necessary monitoring systems under another EPA program, the deadline to begin monitoring and reporting under the Group 3 trading program will be either January 31, 2024 (180 days after the Rule's effective date), for units that report on a year-round basis, or May 1, 2024, for units that report on an ozone season-only basis. *See* 40 CFR 97.1030(b)(1)(iv) and (b)(3).

[23] Under CAA section 307(d)(1)(B), the EPA's revision of a FIP under CAA section 110(c) would normally be subject to the rulemaking procedural requirements of CAA section 307(d), including notice-and-comment procedures, but CAA section 307(d) does not apply ''in the case of any rule or circumstance referred to in subparagraphs (A) or (B) of [APA section 553(b)].'' CAA section 307(d)(1).

revisions needed to implement requirements that are substantively identical to the requirements that would have applied in the absence of the Good Neighbor Plan, or adopting superficially different regulatory revisions to accomplish the same function would serve no purpose and is therefore unnecessary.[24]

With respect to the portions of this action that correct deadlines, each of the deadlines that is incorrect as published in the Good Neighbor Plan precedes the Rule's actual effective date and therefore could not be implemented as published. In the cases of the two deadlines that were incorrect as published because of the timing of the Rule's publication, the amended deadlines of August 4, 2023, and September 30, 2023, are the earliest possible revised deadlines that are both feasible in light of the Good Neighbor Plan's actual effective date and also consistent with the normal timing and sequence of monitoring and reporting activities under the Group 3 trading program regulations. In the case of the deadline that was incorrect as published because of a typographical error, the amended deadline of December 4, 2023, is the same deadline that has already been published in parallel provisions of the Good Neighbor Plan's regulations for other non-EGU industrial sources.[25] Because both the need for the corrections and the specific corrections that should be made are clear, taking comment to allow the public to advocate for not correcting the deadlines or for making different corrections would serve no purpose and is therefore unnecessary.

The regulatory revisions made in this action will take effect on August 4, 2023, the effective date of the Good Neighbor Plan. In general, an agency issuing a rule under APA section 553 must provide for a period of at least 30 days between the rule's dates of publication and effectiveness, but APA section 553(d) includes several exceptions. Under APA section 553(d)(1), an exception applies to a rule that ''grants or recognizes an exemption or relieves a restriction.'' Because the portions of this action that stay the effectiveness of the Good Neighbor Plan's requirements for the sources in certain states grant an exemption (on an interim basis while the stay remains in place), the normal 30-day minimum period between this action's dates of publication and effectiveness is not required. The EPA is making these portions of the action effective as of the Good Neighbor Plan's effective date to comply with the stay orders.

Under APA section 553(d)(3), the normal 30-day minimum period between a rule's dates of publication and effectiveness does not apply ''as otherwise provided by the agency for good cause found and published with the rule.'' With respect to the portions of this action that provide an alternate mechanism for EGUs in states covered by the stay orders to continue to address the states' good neighbor obligations under rules issued before the Good Neighbor Plan and the portions of this action that correct certain deadlines, the EPA finds good cause to make the regulatory revisions effective on August 4, 2023, the effective date of the Good Neighbor Plan, even though that date is less than 30 days after the publication date of this action, for the following reasons. First, the regulatory revisions that facilitate continued implementation of requirements addressing good neighbor obligations under previous rules benefit the public by avoiding the possibility that interruption of the requirements would cause air quality degradation. Second, both these regulatory revisions and the regulatory revisions that correct deadlines benefit the regulated community by clarifying the regulatory requirements that apply in light of the stay orders and the timing of publication of the Good Neighbor Plan. Finally, making the regulatory revisions effective less than 30 days after this action's publication date does not violate the purpose of the normal requirement for a 30-day minimum period, which is ''to give affected parties a reasonable time to adjust their behavior before the final rule takes effect.''[26] The regulatory revisions in this action facilitating continued implementation of previously applicable requirements impose no requirements on any source that differ substantively from the requirements that would have applied to that source in the absence of the Good Neighbor Plan, and the deadline corrections in this action extend the deadlines in the Rule as published. Thus, no affected party needs time to adjust its behavior in preparation for these regulatory revisions.

IV. Request for Comment

As explained in section III of this document, the EPA finds good cause to take this interim final action without prior notice or opportunity for public comment. However, the EPA is providing an opportunity for comment on the content of the amendments. The EPA requests comment on this rule. The EPA is not reopening for comment any provisions of the Good Neighbor Plan, 40 CFR part 52, or 40 CFR part 97 other than the specific provisions that are expressly added or amended in this rule.

V. Statutory and Executive Order Reviews

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

A. Executive Order 12866: Regulatory Planning and Review, as Amended by Executive Order 14094: Modernizing Regulatory Review

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

B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* The Office of Management and Budget (OMB) has previously approved the information collection activities that will apply to the EGUs affected by this action and has assigned OMB control numbers 2060–0258 and 2060–0667. Additional information collection activities that will apply to EGUs and non-EGU industrial sources under the Good Neighbor Plan have been submitted to OMB for approval in conjunction with that rulemaking. This action makes no changes to the information collection activities under the previously approved information collection requests (ICRs) or the additional information collection activities for which approval has been requested in the Good Neighbor Plan's ICRs.

C. Regulatory Flexibility Act (RFA)

This action is not subject to the Regulatory Flexibility Act (RFA), 5.U.S.C. 601–612. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the Administrative Procedure Act (APA), 5 U.S.C. 553, or any other statute. This rule is not subject to notice-and-comment requirements because the

[24] To illustrate, the EPA could in theory preserve the status quo for EGUs in Kentucky and Louisiana by promulgating an entire set of trading program regulations under 40 CFR part 97 replicating the entire set of Group 3 trading program regulations as promulgated in the Revised CSAPR Update without the subsequent revisions promulgated in the Good Neighbor Plan to address states' good neighbor obligations with respect to the 2015 ozone NAAQS. However, the outcome would be substantively identical to the approach the EPA is taking here.

[25] *See* 40 CFR 52.42(g)(2); 40 CFR 52.43(h)(2).

[26] *Omnipoint Corp.* v. *FCC,* 78 F.3d 620, 630 (D.C. Cir. 1996).

Agency has invoked the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in the Unfunded Mandates Reform Act (UMRA), 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. This action imposes no enforceable duty on any state, local, or tribal governments or the private sector. This action simply stays the effectiveness of certain regulatory requirements for certain sources on an interim basis in response to procedural court orders while ensuring that previously applicable regulatory requirements remain in effect.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. This action simply stays the effectiveness of certain regulatory requirements for certain sources on an interim basis in response to procedural court orders while ensuring that previously applicable regulatory requirements remain in effect. 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 responds to court orders issued by the U.S. Courts of Appeals for the Fifth, Sixth, and Eighth Circuits and the EPA lacks discretion to deviate from those orders. The EPA's assessment of health and safety risks for the action establishing the requirements that are being stayed is discussed in Chapter 5 of the regulatory impact analysis for the Good Neighbor Plan.[27]

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

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

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or Indigenous peoples) and low-income populations.

This action responds to court orders issued by the U.S. Courts of Appeals for the Fifth, Sixth, and Eighth Circuits and the EPA lacks discretion to deviate from those orders. The EPA's assessment of environmental justice considerations for the action establishing the requirements that are being stayed is discussed in section VII of the Good Neighbor Plan preamble.[28]

K. Congressional Review Act (CRA)

This action is subject to the Congressional Review Act (CRA), 5 U.S.C. 801–808, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and comment rulemaking procedures are impracticable, unnecessary, or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in section III of this document, including the basis for that finding.

L. Judicial Review

CAA section 307(b)(1) governs judicial review of final actions by the EPA. This section provides, in part, that petitions for review must be filed in the U.S. Court of Appeals for the District of Columbia Circuit (D.C. Circuit): (i) when the agency action consists of ''nationally applicable regulations promulgated, or final actions taken, by the Administrator,'' or (ii) when such action is locally or regionally applicable, but ''such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination.'' For locally or regionally applicable final actions, the CAA reserves to the EPA complete discretion to decide whether to invoke the exception in (ii).[29]

This rulemaking is ''nationally applicable'' within the meaning of CAA section 307(b)(1). In this action, in response to court orders, the EPA is amending on an interim basis the Good Neighbor Plan,[30] which the EPA developed by applying a uniform legal interpretation and common, nationwide analytical methods to address the requirements of CAA section 110(a)(2)(D)(i)(I) concerning interstate transport of pollution (*i.e.,* ''good neighbor'' requirements) for the 2015 ozone NAAQS. Based on that nationwide analysis, the Good Neighbor Plan established FIP requirements for sources in 23 states located across eight EPA Regions and ten federal judicial circuits. Given that this action amends an action implementing the good neighbor requirements of CAA section 110(a)(2)(D)(i)(I) in a large number of states located across the country and given the interdependent nature of interstate pollution transport and the common core of knowledge and analysis involved in promulgating the FIP requirements, this is a ''nationally applicable'' action within the meaning of CAA section 307(b)(1).

In the alternative, to the extent a court finds this action to be locally or regionally applicable, the Administrator is exercising the complete discretion afforded to him under the CAA to make and publish a finding that this action is based on a determination of

[27] *See* Regulatory Impact Analysis for the Final Federal Good Neighbor Plan Addressing Regional Ozone Transport for the 2015 Ozone National Ambient Air Quality Standard (March 2023) at 197–257, available in the docket.

[28] *See* 88 FR 36844–46.

[29] *Sierra Club* v. *EPA,* 47 F.4th 738, 745 (D.C. Cir. 2022) (''EPA's decision whether to make and publish a finding of nationwide scope or effect is committed to the agency's discretion and thus is unreviewable''); *Texas* v. *EPA,* 983 F.3d 826, 834–35 (5th Cir. 2020).

[30] The Good Neighbor Plan is nationally applicable or based on a determination of nationwide scope or effect found and published by the EPA. *See* 88 FR 36859–60.

''nationwide scope or effect'' within the meaning of CAA section 307(b)(1). In this action, in response to court orders, the EPA is amending on an interim basis the Good Neighbor Plan, an action in which the EPA interpreted and applied section 110(a)(2)(D)(i)(I) of the CAA for the 2015 ozone NAAQS based on a common core of nationwide policy judgments and technical analysis concerning the interstate transport of pollutants throughout the continental United States. Based on that nationwide analysis, the Good Neighbor Plan established FIP requirements for sources in 23 states located across eight EPA Regions and ten federal judicial circuits. This action adjusts temporarily the scope and operation of the Good Neighbor Plan for six states in response to court orders, and also implements necessary measures to ensure the status quo is maintained with respect to existing obligations under previously issued regulations (that were themselves nationally applicable or based on a determination of nationwide scope or effect found and published by the EPA [31]). This action also adjusts certain deadlines for all states that remain covered by the Good Neighbor Plan.

The Administrator finds that, like the Good Neighbor Plan which it amends, this action is a matter on which national uniformity in judicial resolution of any petitions for review is desirable, to take advantage of the D.C. Circuit's administrative law expertise, and to facilitate the orderly development of the basic law under the Act. The Administrator also finds that consolidated review of this action in the D.C. Circuit will avoid piecemeal litigation in the regional circuits, further judicial economy, and eliminate the risk of inconsistent results for different states, and that a nationally consistent approach to the CAA's mandate concerning interstate transport of ozone pollution constitutes the best use of Agency resources.

For these reasons, this final action is nationally applicable or, alternatively, the Administrator is exercising the complete discretion afforded to him by the CAA and finds that this final action is based on a determination of nationwide scope or effect for purposes of CAA section 307(b)(1) and is publishing that finding in the **Federal Register**. Under CAA section 307(b)(1), petitions for judicial review of this action must be filed in the D.C. Circuit by September 29, 2023.

[31] *See* 86 FR 23163–64; 81 FR 74585–86.

List of Subjects

40 CFR Part 52

Environmental protection, Administrative practice and procedure, Air pollution control, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone, Particulate matter, Sulfur dioxide.

40 CFR Part 97

Environmental protection, Administrative practice and procedure, Air pollution control, Electric power plants, Nitrogen oxides, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Michael S. Regan,
Administrator.

For the reasons stated in the preamble, parts 52 and 97 of title 40 of the Code of Federal Regulations are amended 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 A—General Provisions

■ 2. Amend § 52.38 by:
■ a. Adding paragraphs (b)(2)(ii)(D) and (b)(2)(iii)(D);
■ b. In paragraph (b)(11)(iii)(D), removing ''and'' after the semicolon;
■ c. In paragraph (b)(14)(i)(F), removing ''and'' after the semicolon;
■ d. Revising paragraph (b)(14)(i)(G);
■ e. Adding paragraph (b)(14)(i)(H);
■ f. Revising paragraphs (b)(14)(iii) introductory text and (b)(14)(iii)(B);
■ g. In paragraph (b)(14)(iii)(C), adding ''Original'' before ''Group 2 allowances'' each time it appears; and
■ h. In paragraph (b)(16)(ii)(B), adding ''and not listed in paragraph (b)(2)(ii)(D)(*2*) of this section'' before ''and any control period''.

The additions and revisions read as follows:

§ 52.38 What are the requirements of the Federal Implementation Plans (FIPs) for the Cross-State Air Pollution Rule (CSAPR) relating to emissions of nitrogen oxides?

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(D) Notwithstanding any other provision of this part:

(*1*) While a stay under paragraph (b)(2)(iii)(D)(*1*) of this section is in effect for the sources in a State and Indian country located within the borders of such State with regard to emissions occurring in a control period in a given year—

(*i*) The provisions of subpart EEEEE of part 97 of this chapter (as modified in any approval of a SIP revision for such State by the Administrator under paragraph (b)(8) of this section) or the provisions of a SIP revision approved for such State by the Administrator under paragraph (b)(9) of this section, if any, shall apply to the sources in such State and areas of Indian country within the borders of such State subject to the State's SIP authority, and the provisions of subpart EEEEE of part 97 of this chapter shall apply to the sources in areas of Indian country within the borders of such State not subject to the State's SIP authority, with regard to emissions occurring in such control period; and

(*ii*) Such State shall be deemed to be listed in this paragraph (b)(2)(ii)(D)(*1*) for purposes of this part and part 97 of this chapter.

(*2*) While a stay under paragraph (b)(2)(iii)(D)(*2*) of this section is in effect for the sources in a State and Indian country located within the borders of such State with regard to emissions occurring in a control period in a given year—

(*i*) The provisions of subpart EEEEE of part 97 of this chapter (as modified in any approval of a SIP revision for such State by the Administrator under paragraph (b)(8) of this section) or the provisions of a SIP revision approved for such State by the Administrator under paragraph (b)(9) of this section, if any, shall apply to the sources in such State and areas of Indian country within the borders of such State subject to the State's SIP authority, and the provisions of subpart EEEEE of part 97 of this chapter shall apply to the sources in areas of Indian country within the borders of such State not subject to the State's SIP authority, with regard to emissions occurring in such control period; and

(*ii*) Such State shall be deemed to be listed in this paragraph (b)(2)(ii)(D)(*2*) for purposes of this part and part 97 of this chapter.

(iii) * * *

(D) Notwithstanding any other provision of this part:

(*1*) The effectiveness of paragraph (b)(2)(iii)(A) of this section is stayed for sources in Kentucky and Louisiana and Indian country located within the borders of such States with regard to emissions occurring in 2023 and thereafter. While a stay under this paragraph (b)(2)(iii)(D)(*1*) is in effect for a State, such State shall be deemed not

to be listed in paragraph (b)(2)(iii)(A) of this section for purposes of part 97 of this chapter for a control period after 2022.

(*2*) The effectiveness of paragraph (b)(2)(iii)(B) of this section is stayed for sources in Arkansas, Mississippi, Missouri, and Texas and Indian country located within the borders of such States with regard to emissions occurring in 2023 and thereafter. While a stay under this paragraph (b)(2)(iii)(D)(*2*) is in effect for a State, such State shall be deemed not to be listed in paragraph (b)(2)(iii)(B) of this section for purposes of part 97 of this chapter.

* * * * *

(14) * * *

(i) * * *

(G) The provisions in § 97.526(e) of this chapter or § 97.826(f) of this chapter (concerning the use of CSAPR NO_X Ozone Season Original Group 2 allowances, CSAPR NO_X Ozone Season Expanded Group 2 allowances, or CSAPR NO_X Ozone Season Group 3 allowances to satisfy requirements to hold CSAPR NO_X Ozone Season Group 1 allowances or the use of CSAPR NO_X Ozone Season Expanded Group 2 allowances or CSAPR NO_X Ozone Season Group 3 allowances to satisfy requirements to hold CSAPR NO_X Ozone Season Original Group 2 allowances); and

(H) The provisions in §§ 97.806(c), 97.824(a) and (d), and 97.825(a) of this chapter (concerning the situations for which compliance requirements are defined in terms of either CSAPR NO_X Ozone Season Original Group 2 allowances or CSAPR NO_X Ozone Season Expanded Group 2 allowances).

* * * * *

(iii) Notwithstanding any discontinuation pursuant to paragraphs (b)(2)(i)(B), (b)(2)(ii)(B) or (C), (b)(2)(iii)(D)(*1*), or (b)(13)(i) of this section of the applicability of subpart BBBBB, EEEEE, or GGGGG of part 97 of this chapter to the sources in a State and areas of Indian country within the borders of the State subject to the State's SIP authority with regard to emissions occurring in any control period, the following provisions shall continue to apply with regard to all CSAPR NO_X Ozone Season Group 1 allowances, CSAPR NO_X Ozone Season Group 2 allowances, and CSAPR NO_X Ozone Season Group 3 allowances at any time allocated for any control period to any source or other entity in the State and areas of Indian country within the borders of the State subject to the State's SIP authority and shall apply to all entities, wherever located, that at any time held or hold such allowances:

* * * * *

(B) The provisions of §§ 97.526(d), 97.826(d) and (e), and 97.1026(e) of this chapter (concerning the conversion of unused CSAPR NO_X Ozone Season Group 1 allowances allocated for specified control periods to different amounts of CSAPR NO_X Ozone Season Original Group 2 allowances or CSAPR NO_X Ozone Season Group 3 allowances, the conversion of unused CSAPR NO_X Ozone Season Original Group 2 allowances allocated for specified control periods to different amounts of CSAPR NO_X Ozone Season Group 3 allowances, and the conversion of unused CSAPR NO_X Ozone Season Group 3 allowances allocated for specified control periods to CSAPR NO_X Ozone Season Expanded Group 2 allowances); and

* * * * *

■ 3. Amend § 52.40 by adding paragraph (c)(4) to read as follows:

§ 52.40 What are the requirements of the Federal Implementation Plans (FIPs) relating to ozone season emissions of nitrogen oxides from sources not subject to the CSAPR ozone season trading program?

* * * * *

(c) * * *

(4) Notwithstanding any other provision of this part, the effectiveness of paragraphs (a) and (b), (c)(1) through (3), and (d) through (g) of this section and §§ 52.41, 52.42, 52.43, 52.44, 52.45, and 52.46 is stayed for sources located in Arkansas, Kentucky, Louisiana, Mississippi, Missouri, and Texas, including Indian country located within the borders of such States.

* * * * *

§ 52.44 [Amended]

■ 4. Amend § 52.44(j)(2) by removing ''June 23, 2023'' and adding in its place ''December 4, 2023''.

Subpart E—Arkansas

■ 5. Amend § 52.184 by:

■ a. Adding paragraph (a)(6); and

■ b. Redesignating paragraph (b) as paragraph (b)(1) and adding paragraph (b)(2).

The additions read as follows:

§ 52.184 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

(a) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (a)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (a)(2) of this section shall apply with regard to such emissions.

(b) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (b)(1) of this section is stayed.

Subpart S—Kentucky

■ 6. Amend § 52.940 by:

■ a. Adding paragraph (b)(6); and

■ b. Redesignating paragraph (c) as paragraph (c)(1) and adding paragraph (c)(2).

The additions read as follows:

§ 52.940 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(b) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (b)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (b)(2) of this section shall apply with regard to such emissions.

(c) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (c)(1) of this section is stayed.

Subpart T—Louisiana

■ 7. Amend § 52.984 by:

■ a. Adding paragraph (d)(6); and

■ b. Redesignating paragraph (e) as paragraph (e)(1) and adding paragraph (e)(2).

The additions read as follows:

§ 52.984 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(d) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (d)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (d)(2) of this section shall apply with regard to such emissions.

(e) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (e)(1) of this section is stayed.

Subpart Z—Mississippi

■ 8. Amend § 52.1284 by:

■ a. Adding paragraph (a)(6); and

■ b. Redesignating paragraph (b) as paragraph (b)(1) and adding paragraph (b)(2).

The additions read as follows:

§ 52.1284 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

(a) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (a)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (a)(2) of this section shall apply with regard to such emissions.

(b) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (b)(1) of this section is stayed.

Subpart AA—Missouri

■ 9. Amend § 52.1326 by:

■ a. Adding paragraph (b)(6); and

■ b. Redesignating paragraph (c) as paragraph (c)(1) and adding paragraph (c)(2).

The additions read as follows:

§ 52.1326 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(b) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (b)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (b)(2) of this section shall apply with regard to such emissions.

(c) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (c)(1) of this section is stayed.

Subpart SS—Texas

■ 10. Amend § 52.2283 by:

■ a. Adding paragraph (d)(6); and

■ b. Redesignating paragraph (e) as paragraph (e)(1) and adding paragraph (e)(2).

The additions read as follows:

§ 52.2283 Interstate pollutant transport provisions; What are the FIP requirements for decreases in emissions of nitrogen oxides?

* * * * *

(d) * * *

(6) Notwithstanding any other provision of this part, the effectiveness of paragraph (d)(3) of this section is stayed with regard to emissions occurring in 2023 and thereafter, provided that while such stay remains in effect, the provisions of paragraph (d)(2) of this section shall apply with regard to such emissions.

(e) * * *

(2) Notwithstanding any other provision of this part, the effectiveness of paragraph (e)(1) of this section is stayed.

PART 97—FEDERAL NO_X BUDGET TRADING PROGRAM, CAIR NO_X AND SO_2 TRADING PROGRAMS, CSAPR NO_X AND SO_2 TRADING PROGRAMS, AND TEXAS SO_2 TRADING PROGRAM

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

Authority: 42 U.S.C. 7401, 7403, 7410, 7426, 7491, 7601, and 7651, *et seq.*

Subpart BBBBB—CSAPR NO_X Ozone Season Group 1 Trading Program

■ 12. Amend § 97.502 by:

■ a. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Expanded Group 2 allowance'';

■ b. Revising the definition of ''CSAPR NO_X Ozone Season Group 2 allowance''; and

■ c. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Original Group 2 allowance''.

The revision and additions read as follows:

§ 97.502 Definitions.

* * * * *

CSAPR NO_X Ozone Season Expanded Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance allocated for a control period after 2022 under subpart EEEEE of this part, § 97.526(d), or § 97.1026(e) to a unit in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) or allocated or auctioned for a control period after 2022 in accordance with the provisions of a SIP revision approved for such a State by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter.

* * * * *

CSAPR NO_X Ozone Season Group 2 allowance means a limited authorization issued and allocated or auctioned by the Administrator under subpart EEEEE of this part, § 97.526(d), or § 97.1026(e), or by a State or permitting authority under a SIP revision approved by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter, to emit one ton of NO_X during a control period of the specified calendar year for which the authorization is allocated or auctioned or of any calendar year thereafter under the CSAPR NO_X Ozone Season Group 2 Trading Program, where each CSAPR NO_X Ozone Season Group 2 allowance is either a CSAPR NO_X Ozone Season Original Group 2 allowance or a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

CSAPR NO_X Ozone Season Original Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance other than a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

■ 13. Amend § 97.526 by:

■ a. In paragraphs (d)(1)(iii) and (iv) and (d)(2)(i), adding ''Original'' before ''Group 2 allowances'' each time it appears;

■ b. Redesignating paragraph (d)(2)(ii) as paragraph (d)(2)(ii)(A);

■ c. In newly redesignated paragraph (d)(2)(ii)(A), removing ''After the Administrator'' and adding in its place ''Except as provided in paragraph (d)(2)(ii)(B) of this section, after the Administrator'';

■ d. Adding paragraph (d)(2)(ii)(B);

■ e. Revising paragraph (e) introductory text;

■ f. In paragraph (e)(1), adding ''Original'' before ''Group 2 allowances'';

■ g. Redesignating paragraph (e)(2) as paragraph (e)(2)(i);

■ h. In newly redesignated paragraph (e)(2)(i), removing ''After the Administrator'' and adding in its place ''Except as provided in paragraph (e)(2)(ii) of this section, after the Administrator''; and

■ i. Adding paragraph (e)(2)(ii).

The additions and revision read as follows:

§ 97.526 Banking and conversion.

* * * * *

(d) * * *

(2) * * *

(ii) * * *

(B) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and §§ 97.826(d)(1) and 97.1026(e), upon any determination that would otherwise result in the initial recordation of a given number of CSAPR NO_X Ozone Season Group 1 allowances in the

compliance account for a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State), the Administrator will not record such CSAPR NO_X Ozone Season Group 1 allowances but instead will allocate and record in such account an amount of CSAPR NO_X Ozone Season Expanded Group 2 allowances for the control period in 2023 computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_X Ozone Season Group 1 allowances divided by the conversion factor determined under paragraph (d)(1)(ii) of this section and further divided by the conversion factor determined under § 97.826(d)(1)(i)(D).

* * * * *

(e) Notwithstanding any other provision of this subpart or any SIP revision approved under § 52.38(b)(4) or (5) of this chapter, CSAPR NO_X Ozone Season Original Group 2 allowances, CSAPR NO_X Ozone Season Expanded Group 2 allowances, or CSAPR NO_X Ozone Season Group 3 allowances may be used to satisfy requirements to hold CSAPR NO_X Ozone Season Group 1 allowances under this subpart as follows, provided that nothing in this paragraph (e) alters the time as of which any such allowance holding requirement must be met or limits any consequence of a failure to timely meet any such allowance holding requirement:

* * * * *

(2) * * *

(ii) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and §§ 97.826(d)(1) and 97.1026(e), the owner or operator of a CSAPR NO_X Ozone Season Group 1 source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) may satisfy a requirement to hold a given number of CSAPR NO_X Ozone Season Group 1 allowances for the control period in 2015 or 2016 by holding instead, in a general account established for this sole purpose, an amount of CSAPR NO_X Ozone Season Expanded Group 2 allowances for the control period in 2021 (or any later control period for which the allowance transfer deadline defined in § 97.802 has passed) computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_X Ozone Season Group 1 allowances divided by the conversion factor determined under paragraph (d)(1)(ii) of this section and further divided by the conversion factor determined under § 97.826(d)(1)(i)(D).

* * * * *

Subpart EEEEE—CSAPR NO_X Ozone Season Group 2 Trading Program

■ 14. Amend § 97.802 by:
■ a. In the definition of ''Allocate or allocation'', removing ''§ 97.526(d), and'' and adding in its place ''§§ 97.526(d), 97.826(d), and 97.1026(e), and'';
■ b. In the definition of ''Common designated representative's assurance level'', paragraph (2), removing ''§ 97.526(d)'' and adding in its place ''§ 97.526(d), § 97.826(d), or § 97.1026(e)'';
■ c. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Expanded Group 2 allowance'';
■ d. Revising the definition of ''CSAPR NO_X Ozone Season Group 2 allowance'';
and
■ e. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Original Group 2 allowance''.

The additions and revision read as follows:

§ 97.802 Definitions.

* * * * *

CSAPR NO_X Ozone Season Expanded Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance allocated for a control period after 2022 under this subpart, § 97.526(d), or § 97.1026(e) to a unit in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) or allocated or auctioned for a control period after 2022 in accordance with the provisions of a SIP revision approved for such a State by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter.

* * * * *

CSAPR NO_X Ozone Season Group 2 allowance means a limited authorization issued and allocated or auctioned by the Administrator under this subpart, § 97.526(d), or § 97.1026(e), or by a State or permitting authority under a SIP revision approved by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter, to emit one ton of NO_X during a control period of the specified calendar year for which the authorization is allocated or auctioned or of any calendar year thereafter under the CSAPR NO_X Ozone Season Group 2 Trading Program, where each CSAPR NO_X Ozone Season Group 2 allowance is either a CSAPR NO_X Ozone Season Original Group 2 allowance or a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

CSAPR NO_X Ozone Season Original Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance other than a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

■ 15. Amend § 97.806 by:
■ a. In paragraph (c)(1)(i), adding ''for such source'' after ''available for deduction'';
■ b. In paragraph (c)(2)(i) introductory text, adding ''for such group'' after ''available for deduction'';
■ c. In paragraph (c)(4), amend the paragraph heading by adding ''*and type*'' after ''*Vintage*''; and
■ d. Adding paragraphs (c)(4)(iii) and (iv).

The additions read as follows:

§ 97.806 Standard requirements.

* * * * *

(c) * * *

(4) * * *

(iii) Except as provided in paragraph (c)(4)(iv) of this section, a CSAPR NO_X Ozone Season Group 2 allowance held for compliance with the requirements under paragraphs (c)(1)(i), (c)(1)(ii)(A), and (c)(2)(i) through (iii) of this section must be a CSAPR NO_X Ozone Season Original Group 2 allowance.

(iv) A CSAPR NO_X Ozone Season Group 2 allowance held for compliance with the requirements under paragraphs (c)(1)(i), (c)(1)(ii)(A), and (c)(2)(i) through (iii) of this section for a source or group of sources in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (or Indian country within the borders of such a State) for a control period after 2022 must be a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

■ 16. Amend § 97.810 by:
■ a. In paragraphs (a)(2)(i) and (ii), removing ''through 2022'' and adding in its place ''and thereafter'';
■ b. Adding paragraphs (a)(8)(iv) through (vi) and (a)(9)(iv) through (vi);
■ c. In paragraphs (a)(12)(i) through (iii), (a)(13)(i) and (ii), (a)(20)(i) through (iii), and (b)(2), removing ''through 2022'' and adding in its place ''and thereafter'';
■ d. Redesignating paragraph (b)(8) as paragraph (b)(8)(i) and adding paragraph (b)(8)(ii);
■ e. Redesignating paragraph (b)(9) as paragraph (b)(9)(i) and adding paragraph (b)(9)(ii); and
■ f. In paragraphs (b)(12), (b)(13), and (b)(20), removing ''through 2022'' and adding in its place ''and thereafter''.

The additions read as follows:

§ 97.810 State NO_X Ozone Season Group 2 trading budgets, new unit set-asides, Indian country new unit set-asides, and variability limits.

(a) * * *

(8) * * *

(iv) The NO_X Ozone Season Group 2 trading budget for 2023 and thereafter is 14,051 tons.

(v) The new unit set-aside for 2023 and thereafter is 283 tons.

(vi) [Reserved]

(9) * * *

(iv) The NO_X Ozone Season Group 2 trading budget for 2023 and thereafter is 14,818 tons.

(v) The new unit set-aside for 2023 and thereafter is 430 tons.

(vi) The Indian country new unit set-aside for 2023 and thereafter is 15 tons.

* * * * *

(b) * * *

(8) * * *

(ii) The variability limit for Kentucky for 2023 and thereafter is 2,951 tons.

(9) * * *

(ii) The variability limit for Louisiana for 2023 and thereafter is 3,112 tons.

* * * * *

■ 17. Amend § 97.811 by:

■ a. Revising paragraph (a)(2);

■ b. In paragraphs (d)(1), (d)(2)(i), (d)(2)(ii)(A) through (C), (d)(3)(i) through (iii), (d)(3)(iv)(A) through (C), (d)(3)(v)(B) and (C), (d)(4)(i) through (iii), (d)(5) introductory text, (d)(5)(i) and (ii), and (d)(6), adding ''Original'' before ''Group 2'' each time it appears;

■ c. In paragraph (e)(1):

■ i. Adding ''and not listed in § 52.38(b)(2)(ii)(D)(*2*) of this chapter'' before ''(and Indian country''; and

■ ii. Adding ''Original'' before ''Group 2'' each time it appears; and

■ d. In paragraphs (e)(2)(i), (e)(2)(ii)(A) through (C), (e)(3)(i) through (iii), (e)(3)(iv)(A) through (C), (e)(3)(v)(B) and (C), (e)(4)(i) through (iii), (e)(5) introductory text, (e)(5)(i) and (ii), and (e)(6), adding ''Original'' before ''Group 2'' each time it appears.

The revision reads as follows:

§ 97.811 Timing requirements for CSAPR NO_X Ozone Season Group 2 allowance allocations.

(a) * * *

(2) Notwithstanding paragraph (a)(1) of this section:

(i) If a unit provided an allocation of CSAPR NO_X Ozone Season Original Group 2 allowances in the applicable notice of data availability issued under paragraph (a)(1) of this section does not operate, starting after 2016, during the control period in two consecutive years, such unit will not be allocated the CSAPR NO_X Ozone Season Original Group 2 allowances provided in such notice for the unit for the control periods in the fifth year after the first such year and in each year after that fifth year.

(ii) If a unit provided an allocation of CSAPR NO_X Ozone Season Expanded Group 2 allowances in the applicable notice of data availability issued under paragraph (a)(1) of this section does not operate, starting after 2020, during the control period in two consecutive years, such unit will not be allocated the CSAPR NO_X Ozone Season Expanded Group 2 allowances provided in such notice for the unit for the control periods in the fifth year after the first such year and in each year after that fifth year.

(iii) All CSAPR NO_X Ozone Season Group 2 allowances that would otherwise have been allocated to a unit described in paragraph (a)(2)(i) or (ii) of this section will be allocated to the new unit set-aside for the State where such unit is located and for the respective years involved. If such unit resumes operation, the Administrator will allocate CSAPR NO_X Ozone Season Group 2 allowances to the unit in accordance with paragraph (b) of this section.

* * * * *

■ 18. Amend § 97.816 by revising paragraph (c) to read as follows:

§ 97.816 Certificate of representation.

* * * * *

(c) A certificate of representation under this section, § 97.516, or § 97.1016 that complies with the provisions of paragraph (a) of this section except that it contains the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3'' in place of the phrase ''CSAPR NO_X Ozone Season Group 2'' in the required certification statements will be considered a complete certificate of representation under this section, and the certification statements included in such certificate of representation will be interpreted for purposes of this subpart as if the phrase ''CSAPR NO_X Ozone Season Group 2'' appeared in place of the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3''.

■ 19. Amend § 97.818 by redesignating paragraph (f) as paragraph (f)(1) and adding paragraph (f)(2) to read as follows:

§ 97.818 Delegation by designated representative and alternate designated representative.

* * * * *

(f) * * *

(2) A notice of delegation submitted under paragraph (c) of this section or § 97.1018(c) that complies with the provisions of paragraph (c) of this section except that it contains the terms ''40 CFR 97.1018(d)'' and ''40 CFR 97.1018'' in place of the terms ''40 CFR 97.818(d)'' and ''40 CFR 97.818'', respectively, in the required certification statements will be considered a valid notice of delegation submitted under paragraph (c) of this section, and the certification statements included in such notice of delegation will be interpreted for purposes of this subpart as if the terms ''40 CFR 97.818(d)'' and ''40 CFR 97.818'' appeared in place of the terms ''40 CFR 97.1018(d)'' and ''40 CFR 97.1018'', respectively.

■ 20. Amend § 97.820 by:

■ a. Revising paragraphs (c)(1)(iv) and (c)(2)(iv); and

■ b. Redesignating paragraph (c)(5)(vi) as paragraph (c)(5)(vi)(A) and adding paragraph (c)(5)(vi)(B).

The revisions and addition read as follows:

§ 97.820 Establishment of compliance accounts, assurance accounts, and general accounts.

* * * * *

(c) * * *

(1) * * *

(iv) An application for a general account under paragraph (c)(1) of this section, § 97.520(c)(1), or § 97.1020(c)(1) that complies with the provisions of paragraph (c)(1) of this section except that it contains the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3'' in place of the phrase ''CSAPR NO_X Ozone Season Group 2'' in the required certification statement will be considered a complete application for a general account under paragraph (c)(1) of this section, and the certification statement included in such application for a general account will be interpreted for purposes of this subpart as if the phrase ''CSAPR NO_X Ozone Season Group 2'' appeared in place of the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3''.

(2) * * *

(iv) A certification statement submitted in accordance with paragraph (c)(2)(ii) of this section that contains the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3'' will be interpreted for purposes of this subpart as if the phrase ''CSAPR NO_X Ozone Season Group 2'' appeared in place of the phrase ''TR NO_X Ozone Season'' or the phrase ''CSAPR NO_X Ozone Season Group 3''.

* * * * *

(5) * * *

(vi) * * *

(B) A notice of delegation submitted under paragraph (c)(5)(iii) of this section or § 97.1020(c)(5)(iii) that complies with the provisions of paragraph (c)(5)(iii) of

this section except that it contains the terms ''40 CFR 97.1020(c)(5)(iv)'' and ''40 CFR 97.1020(c)(5)'' in place of the terms ''40 CFR 97.820(c)(5)(iv)'' and ''40 CFR 97.820(c)(5)'', respectively, in the required certification statements will be considered a valid notice of delegation submitted under paragraph (c)(5)(iii) of this section, and the certification statements included in such notice of delegation will be interpreted for purposes of this subpart as if the terms ''40 CFR 97.820(c)(5)(iv)'' and ''40 CFR 97.820(c)(5)'' appeared in place of the terms ''40 CFR 97.1020(c)(5)(iv)'' and ''40 CFR 97.1020(c)(5)'', respectively.

* * * * *

■ 21. Amend § 97.821 by:
■ a. Redesignating paragraph (e) as paragraph (e)(1);
■ b. In newly redesignated paragraph (e)(1), adding ''Original'' before ''Group 2 allowances'' each time it appears; and
■ c. Adding paragraph (e)(2).

The addition reads as follows:

§ 97.821 Recordation of CSAPR NO_X Ozone Season Group 2 allowance allocations and auction results.

* * * * *

(e) * * *

(2) By September 5, 2023, the Administrator will record in each CSAPR NO_X Ozone Season Group 2 source's compliance account the CSAPR NO_X Ozone Season Expanded Group 2 allowances allocated to the CSAPR NO_X Ozone Season Group 2 units at the source in accordance with § 97.811(a) for the control periods in 2023 and 2024.

* * * * *

■ 22. Amend § 97.824 by:
■ a. In paragraph (a)(1), removing ''and'' after the semicolon;
■ b. Adding paragraphs (a)(3) and (4);
■ c. In paragraph (c)(2)(ii), removing ''§ 97.526(d), in'' and adding in its place ''§ 97.526(d), § 97.826(d), or § 97.1026(e), in''; and
■ d. Revising paragraph (d).

The additions and revision read as follows:

§ 97.824 Compliance with CSAPR NO_X Ozone Season Group 2 emissions limitation.

(a) * * *

(3) Are CSAPR NO_X Ozone Season Original Group 2 allowances, if the deductions are not for compliance with the CSAPR NO_X Ozone Season Group 2 emissions limitation of a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022; and

(4) Are CSAPR NO_X Ozone Season Expanded Group 2 allowances, if the deductions are for compliance with the CSAPR NO_X Ozone Season Group 2 emissions limitation of a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022.

* * * * *

(d) *Deductions for excess emissions.* After making the deductions for compliance under paragraph (b) of this section for a control period in a year in which the CSAPR NO_X Ozone Season Group 2 source has excess emissions, the Administrator will deduct from the source's compliance account an amount of CSAPR NO_X Ozone Season Group 2 allowances, allocated or auctioned for a control period in a prior year or the control period in the year of the excess emissions or in the immediately following year, equal to two times the number of tons of the source's excess emissions, provided that—

(1) The allowances deducted shall be CSAPR NO_X Ozone Season Original Group 2 allowances, if the excess emissions are not from a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022; and

(2) The allowances deducted shall be CSAPR NO_X Ozone Season Expanded Group 2 allowances, if the excess emissions are from a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022.

* * * * *

■ 23. Amend § 97.825 by:
■ a. In paragraph (a)(1), removing ''and'' after the semicolon; and
■ b. Adding paragraphs (a)(3) and (4).

The additions read as follows:

§ 97.825 Compliance with CSAPR NO_X Ozone Season Group 2 assurance provisions.

(a) * * *

(3) Are CSAPR NO_X Ozone Season Original Group 2 allowances, if the deductions are not for compliance with the CSAPR NO_X Ozone Season Group 2 assurance provisions by the owners and operators of a group of sources in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022; and

(4) Are CSAPR NO_X Ozone Season Expanded Group 2 allowances, if the deductions are for compliance with the CSAPR NO_X Ozone Season Group 2 assurance provisions by the owners and operators of a group of sources in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) for a control period after 2022.

* * * * *

■ 24. Amend § 97.826 by:
■ a. In paragraphs (d)(1)(i)(A) and (D), (d)(1)(ii)(A), (d)(1)(iii)(A), (d)(1)(iv)(A) and (B), and (d)(2)(ii), adding ''Original'' before ''Group 2 allowances'' each time it appears;
■ b. Redesignating paragraph (d)(3) as paragraph (d)(3)(i);
■ c. In newly redesignated paragraph (d)(3)(i):
■ i. Removing ''After the Administrator'' and adding in its place ''Except as provided in paragraph (d)(3)(ii) of this section, after the Administrator''; and
■ ii. Adding ''Original'' before ''Group 2 allowances'' each time it appears;
■ d. Adding paragraph (d)(3)(ii);
■ e. In paragraph (e)(1) introductory text, adding ''or (D)'' before ''of this chapter'';
■ f. In paragraphs (e)(1)(i), (e)(1)(ii)(A), (e)(1)(iii) and (iv), (e)(1)(v)(B), and (e)(2), adding ''Original'' before ''Group 2 allowances'' each time it appears;
■ g. Revising paragraph (f) introductory text;
■ h. Redesignating paragraph (f)(1) as paragraph (f)(1)(i);
■ i. In newly redesignated paragraph (f)(1)(i):
■ i. Removing ''After the Administrator'' and adding in its place ''Except as provided in paragraph (f)(1)(ii) of this section, after the Administrator''; and
■ ii. Adding ''Original'' before ''Group 2 allowances'' each time it appears;
■ j. Adding paragraph (f)(1)(ii); and
■ k. In paragraph (f)(2):
■ i. Adding ''and not listed in § 52.38(b)(ii)(D)(*2*) of this chapter'' before ''(and Indian country''; and
■ ii. Adding ''Original'' before ''Group 2 allowances'' each time it appears.

The additions and revision read as follows:

§ 97.826 Banking and conversion.

* * * * *

(d) * * *

(3) * * *

(ii) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and § 97.1026(e), upon any determination that would otherwise result in the initial recordation of a given number of CSAPR NO_X Ozone Season Original Group 2 allowances in the compliance account for a source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State), the Administrator will not record such CSAPR NO_X Ozone Season Original Group 2 allowances but

instead will allocate and record in such account an amount of CSAPR NO_X Ozone Season Expanded Group 2 allowances for the control period in 2023 computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_X Ozone Season Original Group 2 allowances divided by the conversion factor determined under paragraph (d)(1)(i)(D) of this section.

* * * * *

(f) Notwithstanding any other provision of this subpart or any SIP revision approved under § 52.38(b)(8) or (9) of this chapter, CSAPR NO_X Ozone Season Expanded Group 2 allowances or CSAPR NO_X Ozone Season Group 3 allowances may be used to satisfy requirements to hold CSAPR NO_X Ozone Season Original Group 2 allowances under this subpart as follows, provided that nothing in this paragraph (f) alters the time as of which any such allowance holding requirement must be met or limits any consequence of a failure to timely meet any such allowance holding requirement:

(1) * * *

(ii) After the Administrator has carried out the procedures set forth in paragraph (d)(1) of this section and § 97.1026(e), the owner or operator of a CSAPR NO_X Ozone Season Group 2 source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) may satisfy a requirement to hold a given number of CSAPR NO_X Ozone Season Original Group 2 allowances for a control period in 2017 through 2020 by holding instead, in a general account established for this sole purpose, an amount of CSAPR NO_X Ozone Season Expanded Group 2 allowances for the control period in 2023 (or any later control period for which the allowance transfer deadline defined in § 97.802 has passed) computed as the quotient, rounded up to the nearest allowance, of such given number of CSAPR NO_X Ozone Season Original Group 2 allowances divided by the conversion factor determined under paragraph (d)(1)(i)(D) of this section.

* * * * *

■ 25. Amend § 97.830 by revising paragraph (b)(1) to read as follows:

§ 97.830 General monitoring, recordkeeping, and reporting requirements.

* * * * *

(b) * * *

(1)(i) May 1, 2017, for a unit other than a unit described in paragraph (b)(1)(ii) of this section;

(ii) May 1, 2023, for a unit that did not commence commercial operation at least 180 calendar days before September 30, 2020 and that is located in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State);

* * * * *

■ 26. Amend § 97.834 by revising paragraph (d)(2)(i) to read as follows:

§ 97.834 Recordkeeping and reporting.

* * * * *

(d) * * *

(2) * * *

(i)(A) The calendar quarter covering May 1, 2017 through June 30, 2017, for a unit other than a unit described in paragraph (d)(2)(i)(B) of this section;

(B) The calendar quarter covering May 1, 2023 through June 30, 2023, for a unit that did not commence commercial operation at least 180 calendar days before September 30, 2020 and that is located in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State);

* * * * *

Subpart GGGGG—CSAPR NO_X Ozone Season Group 3 Trading Program

■ 27. Amend § 97.1002 by:

■ a. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Expanded Group 2 allowance'';

■ b. Revising the definition of ''CSAPR NO_X Ozone Season Group 2 allowance''; and

■ c. Adding in alphabetical order a definition of ''CSAPR NO_X Ozone Season Original Group 2 allowance''.

The additions and revision read as follows:

§ 97.1002 Definitions.

* * * * *

CSAPR NO_X Ozone Season Expanded Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance allocated for a control period after 2022 under subpart EEEEE of this part, § 97.526(d), or § 97.1026(e) to a unit in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) or allocated or auctioned for a control period after 2022 in accordance with the provisions of a SIP revision approved for such a State by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter.

* * * * *

CSAPR NO_X Ozone Season Group 2 allowance means a limited authorization issued and allocated or auctioned by the Administrator under subpart EEEEE of this part, § 97.526(d), or § 97.1026(e), or by a State or permitting authority under a SIP revision approved by the Administrator under § 52.38(b)(7), (8), or (9) of this chapter, to emit one ton of NO_X during a control period of the specified calendar year for which the authorization is allocated or auctioned or of any calendar year thereafter under the CSAPR NO_X Ozone Season Group 2 Trading Program, where each CSAPR NO_X Ozone Season Group 2 allowance is either a CSAPR NO_X Ozone Season Original Group 2 allowance or a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

CSAPR NO_X Ozone Season Original Group 2 allowance means a CSAPR NO_X Ozone Season Group 2 allowance other than a CSAPR NO_X Ozone Season Expanded Group 2 allowance.

* * * * *

■ 28. Amend § 97.1026 by:

■ a. Revising the section heading; and

■ b. Adding paragraphs (e) and (f).

The revision and additions read as follows:

§ 97.1026 Banking and conversion; bank recalibration.

* * * * *

(e) Notwithstanding any other provision of this subpart, by September 18, 2023, the Administrator will temporarily suspend acceptance of CSAPR NO_X Ozone Season Group 3 allowance transfers submitted under § 97.1022 and, before resuming acceptance of such transfers, will take the actions in paragraphs (e)(1) and (2) of this section with regard to every compliance account for a CSAPR NO_X Ozone Season Group 3 source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State):

(1) The Administrator will deduct all CSAPR NO_X Ozone Season Group 3 allowances allocated for the control periods in 2021 and 2022 from each such compliance account.

(2) For each CSAPR NO_X Ozone Season Group 3 allowance deducted from a given source's compliance account under paragraph (e)(1) of this section, the Administrator will allocate to the source and record in the source's compliance account one CSAPR NO_X Ozone Season Expanded Group 2 allowance for the control period in 2023.

(f) Notwithstanding any other provision of this subpart, CSAPR NO_X Ozone Season Expanded Group 2 allowances may be used to satisfy requirements to hold CSAPR NO_X Ozone Season Group 3 allowances under this subpart as follows, provided that nothing in this paragraph (f) alters the time as of which any such allowance

holding requirement must be met or limits any consequence of a failure to timely meet any such allowance holding requirement:

(1) After the Administrator has carried out the procedures set forth in paragraph (e) of this section, the owner or operator of a CSAPR NO_X Ozone Season Group 3 source in a State listed in § 52.38(b)(2)(ii)(D)(*1*) of this chapter (and Indian country within the borders of such a State) may satisfy a requirement to hold a given number of CSAPR NO_X Ozone Season Group 3 allowances for the control period in 2021 or 2022 by holding instead, in a general account established for this sole purpose, an equal amount of CSAPR NO_X Ozone Season Expanded Group 2 allowances for the control period in 2023 (or any later control period for which the allowance transfer deadline defined in § 97.802 has passed).

(2) [Reserved]

■ 29. Amend § 97.1034 by:

■ a. In paragraph (d)(2)(i)(C), removing ''June'' and adding in its place ''September'';

■ b. In paragraph (d)(3), revising the first sentence; and

■ c. In paragraph (d)(4), adding a second sentence.

The revision and addition read as follows:

§ 97.1034 Recordkeeping and reporting.

* * * * *

(d) * * *

(3) The designated representative shall submit each quarterly report to the Administrator within 30 days after the end of the calendar quarter covered by the report, except that quarterly reports required for the calendar quarter covering May 1, 2023, through June 30, 2023, shall be submitted by August 4, 2023. * * *

(4) * * * Notwithstanding the provisions of §§ 75.64(a), 75.73(f)(1), 97.434(d)(2), 97.634(d)(2), and 97.734(d)(2), the deadline for the designated representative of such a unit to submit the quarterly reports required under such additional programs for the calendar quarter covering May 1, 2023, through June 30, 2023, shall be August 4, 2023.

* * * * *

[FR Doc. 2023–14180 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–5538–N]

Medicare Program; Alternative Payment Model (APM) Incentive Payment Advisory for Clinicians—Request for Current Billing Information for Qualifying APM Participants

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Payment advisory.

SUMMARY: This advisory is to alert certain clinicians who are Qualifying APM participants (QPs) and eligible to receive an Alternative Payment Model (APM) Incentive Payment that CMS does not have the current billing information needed to disburse the payment. This advisory provides information to these clinicians on how to update their billing information to receive this payment.

DATES: Updated billing information must be received no later than September 1, 2023 (see **SUPPLEMENTARY INFORMATION** for details).

FOR FURTHER INFORMATION CONTACT: Tanya Dorm, (410) 786–2216.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare Quality Payment Program, an eligible clinician who participates in an Advanced Alternative Payment Model (APM) and meets the applicable payment amount or patient count thresholds for a performance year is a Qualifying APM Participant (QP) for that year. For payment years 2019 through 2024, which corresponds to Performance Periods for 2017 through 2022, an eligible clinician who is a QP for a year based on their performance in a QP Performance Period earns a 5 percent lump sum APM Incentive Payment that is paid in a payment year that occurs 2 years after the QP Performance Period. The amount of the APM Incentive Payment is equal to 5 percent of the estimated aggregate paid amounts for covered professional services furnished by the QP during the calendar year immediately preceding the payment year.

II. Provisions of the Advisory

The Centers for Medicare & Medicaid Services (CMS) has identified those eligible clinicians who earned an APM Incentive Payment for the calendar year (CY) 2023 payment year based on their QP status for the 2021 QP performance period.

When CMS disbursed the CY 2023 APM Incentive Payments, CMS was unable to verify current Medicare billing information for some QPs and was therefore unable to issue payment. In order to successfully disburse the APM Incentive Payment, CMS is requesting assistance in identifying current Medicare billing information for these QPs in accordance with 42 CFR 414.1450(c)(8).

CMS has compiled a list of QPs we have identified as having unverified billing information. These QPs, and any others who anticipated receiving an APM Incentive Payment but have not, should follow the instructions to provide CMS with updated billing information at the following web address: *https://qpp.cms.gov/resources/resource-library.*

If you have any questions concerning submission of information through the website, please contact the Quality Payment Program Help Desk at 1–866–288–8292.

All submissions must be received no later than September 1, 2023. After that time, any claims to an APM Incentive Payment for the CY 2023 payment period based on an eligible clinicians' QP status for the 2021 QP performance period will be forfeited.

All submissions received by September 1, 2023, will be processed together on one date as soon as practicable after September 1, 2023. CMS will not notify the submitter if we are unable to process the APM Incentive Payment based on the billing information submitted for an eligible clinician.

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Dated: July 25, 2023.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–16140 Filed 7–28–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 10, 17, and 21

[Docket No. FWS–HQ–MB–2022–0036; FXMB12320900000//234//FF09M30000]

RIN 1018–BG04

General Provisions; Revised List of Migratory Birds

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), revise the List of Birds protected by the Migratory Bird Treaty Act (MBTA) by both adding and removing species and changing names to conform to accepted use by the scientific community. Reasons for the changes to the list include adding species based on new taxonomy and new evidence of natural occurrence in the United States or U.S. territories, removing species no longer known to occur within the United States or U.S. territories, and changing names to reflect currently accepted taxonomy and nomenclature. The net increase of 13 species (16 added and 3 removed) brings the total number of species protected by the MBTA to 1,106. We also revise the scientific name of a species subject to specific migratory-bird-permit regulations and revise corresponding entries for several migratory bird species that are also listed on the List of Endangered and Threatened Wildlife under the Endangered Species Act to reflect currently accepted taxonomy and nomenclature. We are taking this action because an accurate and up-to-date list of species protected by the MBTA is essential for public-notification, regulatory, and law-enforcement purposes and to ensure consistency in the use of common and scientific names across Service regulations.

DATES: This rule is effective August 30, 2023.

FOR FURTHER INFORMATION CONTACT: Eric L. Kershner, Chief, Division of Bird Conservation, Permits, and Regulations; Migratory Bird Program; U.S. Fish and Wildlife Service; MS: MB; 5275 Leesburg Pike, Falls Church, VA 22041–3803; (703) 358–2376; or Elizabeth Maclin, Chief, Division of Restoration and Recovery; Ecological Services; U.S. Fish and Wildlife Service; MS: ES; 5275 Leesburg Pike, Falls Church, VA 22041–3803; (703) 358–2646. 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:

I. List of Migratory Birds (50 CFR 10.13)

Statutory Authority of the Service for Maintaining and Revising the List of Birds Protected by the MBTA

The Service (as delegated by the Secretary) has the statutory authority and responsibility for implementing and enforcing the MBTA (16 U.S.C. 703–712), the Fish and Wildlife Improvement Act of 1978 (Pub. L. 95–616; 16 U.S.C. 742l), and the Fish and Wildlife Act of 1956 (16 U.S.C. 742a–742j, not including 742d–1). The MBTA implements conventions (bilateral treaties) between the United States and four neighboring countries for the protection of migratory birds, as follows:

(1) *Canada:* Convention between the United States and Great Britain [on behalf of Canada] for the Protection of Migratory Birds, August 16, 1916, 39 Stat. 1702 (T.S. No. 628), as amended by Protocol between the Government of the United States and the Government of Canada Amending the 1916 Convention between the United Kingdom and the United States of America for the Protection of Migratory Birds, Sen. Treaty Doc. 104–28 (December 14, 1995);

(2) *Mexico:* Convention between the United States and Mexico for the Protection of Migratory Birds and Game Mammals, February 7, 1936, 50 Stat. 1311 (T.S. No. 912), as amended March 10, 1972 (23 U.S.T. 260; T.I.A.S. 7302), and by Protocol with Mexico amending Convention for Protection of Migratory Birds and Game Mammals, Sen. Treaty Doc. 105–26 (May 5, 1997);

(3) *Japan:* Convention between the Government of the United States of America and the Government of Japan for the Protection of Migratory Birds and Birds in Danger of Extinction, and Their Environment, March 4, 1972, 25 U.S.T. 3329 (T.I.A.S. No. 7990); and

(4) *Russia:* Convention between the United States of America and the Union of Soviet Socialist Republics Concerning the Conservation of Migratory Birds and Their Environment (Russia), November 19, 1976, 29 U.S.T. 4647 (T.I.A.S. No. 9073).

What is the purpose of this rulemaking?

Our purpose is to inform the public of updates to the list of species protected by the MBTA and its implementing regulations. These regulations are found in title 50 of the Code of Federal Regulations (CFR) at parts 10, 20, 21, and 92. We regulate the taking, possession, transportation, sale, purchase, barter, exportation, and importation of birds protected by the MBTA. An accurate and up-to-date list of species protected by the MBTA is essential for notifying the public and other Federal, State, and Tribal agencies of which species are subject to regulatory protections.

Why is this amendment of the list of birds protected by the MBTA necessary?

The amendments we are adopting in this final rule are needed to:

(1) Add 11 species based on new distributional records documenting their natural occurrence in the United States or U.S. territories since 2019;

(2) Add five species newly recognized as a result of recent taxonomic changes;

(3) Remove three species not known to occur within the boundaries of the United States or U.S. territories as a result of recent taxonomic changes;

(4) Change the common (English) names of eight species to conform to accepted use; and

(5) Change the scientific names of 22 species to conform to accepted use.

The List of Birds Protected by the MBTA (50 CFR 10.13) was last revised on April 16, 2020 (85 FR 21282). The amendments in this rule were necessitated by three published supplements and one published addendum to a supplement to the 7th (1998) edition of the American Ornithologists' Union (AOU, now recognized as the American Ornithological Society (AOS)) Checklist of North American Birds (AOS 2020a, 2020b, 2021, and 2022) and the 2016, 2019, and 2021 publications of the Clements Checklist of Birds of the World (Clements et al. 2016, 2019, 2021).

What scientific authorities are used to amend the list of birds protected by the MBTA?

Although bird names (common and scientific) are relatively stable, staying current with standardized use is necessary to avoid confusion in communications. In making our determinations, we primarily relied on the AOS's Checklist of North American birds (AOU 1998), as amended annually (AOS 2020a, 2020b, 2021, and 2022), on matters of taxonomy, nomenclature, and the sequence of species and other higher taxonomic categories (Orders, Families, Subfamilies) for species that occur in North America. The AOS Checklist of

North American Birds (Checklist), developed by the AOS Committee on Classification and Nomenclature, has been the recognized taxonomic authority for North American birds since publication of the first edition of the Checklist in 1886. The committee compiles the taxonomic foundation for ornithology in North America; they evaluate and publish the latest scientific developments in the systematics, classification, nomenclature, and distribution of North American birds. Thus, the AOS's Checklist represents the best scientific information available for developing the North American component of this List of Birds Protected by the MBTA. In keeping with the increasing numbers of study areas on which taxonomy relies, the committee incorporates expertise in phylogenetics, genomics, vocalizations, morphology, behavior, and geographical distribution, as well as general ornithological knowledge. The AOS Checklist contains all bird species that have occurred in North America from the Arctic through Panama, including the West Indies and the Hawaiian Islands, and includes distributional information for each species, which specifies whether the species is known to occur in the United States. The committee also keeps and updates a list of species known to occur in the United States.

For the species that occur in the U.S. territories outside the geographic area covered by the AOS Checklist, we relied primarily on the Clements Checklist of Birds of the World (Clements Checklist) (Clements et al. 2007), the Clements Checklist 2016, 2019, and 2021 installment of updates and corrections (Clements et al. 2016, 2019, 2021), and other peer-reviewed literature where appropriate. The Clements Checklist is a list of all known bird species in the world and is maintained and updated annually by the Cornell Laboratory of Ornithology (CLO). The CLO relies on different regional ornithological authorities to compile the Clements Checklist, using the AOS for the western hemisphere. Taxonomy and nomenclature are the primary focus of the Clements Checklist. Range descriptions are maintained and updated based on the best available information but do not include records of vagrancy.

Although we primarily rely on the above sources, when informed taxonomic opinion is inconsistent or controversial, we evaluate available published and unpublished information and come to our own conclusion regarding the validity of taxa and whether to include taxonomic changes. We also evaluate available documentation for new species documented to occur naturally in the United States or U.S. territories and come to our own conclusion regarding whether to add those species to the List of Birds Protected by the MBTA.

For this update, we reviewed 13 species that were added to the AOS Checklist based on new natural distribution in the United States or U.S. territories (AOS 2020a, 2021, and 2022). Based on the available evidence and criteria to identify individual species that qualify for protection by the MBTA (see below), we add 11 of those 13 species. We elected not to add 2 of the 13 species, Red-backed Shrike, *Lanius collurio,* and Graylag Goose, *Anser anser.*

When we reviewed the evidence for the record of Red-backed Shrike that was accepted by the AOS, along with an analysis from an AOS committee member, we learned the shrike in question was a juvenile. The best current information does not reliably demonstrate how juveniles of Red-backed Shrike can be distinguished from juvenile Red-tailed Shrikes, *Lanius phoenicuroides,* and the two species are also known to commonly hybridize. While there are descriptions available in the literature of adult hybrids of these two shrike species, this is not the case for juvenile hybrids. Therefore, due to the challenges in identification, we decided not to include this record at this time. We may revisit this decision to exclude the Red-backed Shrike in a subsequent update to the list if a reliable method of distinguishing juveniles and hybrid juveniles of the two species is devised.

Regarding the Graylag Goose, we considered the regulatory implications of adding it to the list because the species intermixes with other goose species that may be hunted under the Service's and State hunting regulations. We decided not to add the species at this time while we consider those regulatory implications, similar to how we treated the split of Cackling Goose, *Branta hutchinsii,* from Canada Goose, *Branta canadensis,* in 2013 (78 FR 65844; November 1, 2013), later adding the species to the 50 CFR 10.13 list in 2020 (85 FR 21282; April 16, 2020). We may reconsider adding this species in a subsequent update to the list once the frequency of the species occurring in the United States is better understood and what the implications to hunting regulations in 50 CFR part 20 would be. We reserve the right to revisit these decisions if additional information becomes available.

As is customary with species subject to our hunting regulations at 50 CFR part 20, we consulted with the Pacific, Central, Mississippi, and Atlantic Flyway Councils in our review of the taxonomic split of Mexican Duck from Mallard. We also reviewed published scientific literature regarding the Mallard split (Bellrose 1976; Hubbard 1977; Brown 1985; Lavretsky et al. 2015, 2019; AOS 2020a). Ultimately, we concluded to add Mexican Duck to the list.

What criteria are used to identify individual species protected by the MBTA?

A species qualifies for protection under the MBTA by meeting one or more of the following criteria:

(1) It occurs in the United States or U.S. territories as the result of natural biological or ecological processes and is currently, or was previously listed as, a species or a member of a family protected by one of the four international treaties or their amendments. A naturally occurring species is protected by the MBTA as a member of a protected family even if the species is ecologically nonmigratory, meaning it does not exhibit seasonal movements (also known as a resident species). For example, the Bushtit (*Psaltriparus minimus*) is a resident, nonmigratory species and is included in 50 CFR 10.13 because it occurs in a family (Aegithalidae) that is protected by the bilateral treaty with Canada. Any species that occurs in the United States or U.S. territories solely as a result of intentional or unintentional human-assisted introduction does not qualify for the MBTA list, regardless of whether the family the species belongs to is listed in any of the treaties, unless:

- It was either native to the United States or its territories and extant in 1918; or
- It was extirpated after 1918 throughout its range in the United States and its territories, and, after such extirpation, it was reintroduced in the United States or its territories as part of a program carried out by a Federal agency.

(2) Revised taxonomy results in it being newly split from a species that was previously on the list, and the new species occurs in the United States or U.S. territories as the result of natural biological or ecological processes. If a newly recognized native species is considered extinct (following the classification of the American Ornithological Society (AOS) or, for species not covered by the AOS, the Clements Checklist or peer-reviewed literature), that species will still be

included if either of the following criteria apply:

- The species resembles extant species included in the list that may be affected by trade or other commercial activities if the species is not included; or
- Not including the species may create difficulties implementing the MBTA and its underlying conventions.

(3) New evidence exists for its natural occurrence in the United States or U.S. territories resulting from new or natural distributional changes and the species belongs to a protected family. Records must be documented, accepted, and published by the AOS committee. For the U.S. Pacific territories that fall outside the geographic scope of the AOS and for which there is no identified ornithological authority, new evidence of a species' natural occurrence will be based on the Clements Checklist and then published peer-reviewed literature, in that order. Records and the evidence supporting their acceptance by the AOS, Clements Checklist, or peer-reviewed literature are reviewed independently by the Service before we propose adding the species to the list.

In accordance with the Migratory Bird Treaty Reform Act of 2004 (MBTRA) (Pub. L. 108–447, December 8, 2004, 118 Stat. 2809, 3071–72), we only include migratory bird species that are native to the United States or U.S. territories. A native migratory bird species is one that is present as a result of natural biological or ecological processes. The list at 50 CFR 10.13 does not include nonnative species that occur in the United States or U.S. territories solely as a result of intentional or unintentional human-assisted introduction(s). An amended list of the nonnative bird species that have been introduced by humans into the United States or U.S. territories and to which the MBTA does not apply was published in the **Federal Register** on April 16, 2020 (85 FR 21262), with a correction published on May 3, 2021 (86 FR 23422).

What species are not protected by the Migratory Bird Treaty Act?

The MBTA does not apply to:

(1) Nonnative species introduced into the United States or U.S. territories by means of intentional or unintentional human assistance that belong to families or groups covered by the Canadian, Mexican, or Russian Conventions. Note, though, that native species that are introduced into parts of the United States where they are not native are still protected under the MBTA regardless of where they occur in the United States or U.S. territories.

(2) Species native or nonnative to the United States or U.S. territories that either belong to families or groups not referred to in the Canada, Mexico, and Russia Conventions or are not included by species name in the Japan Convention. This includes the Tinamidae (tinamous), Megapodiidae (megapodes), Cracidae (chachalacas), Odontophoridae (New World quail), Phasianidae (grouse, ptarmigan, and turkeys), Pteroclidae (sandgrouse), Heliornithidae (finfoots), Burhinidae (thick-knees), Glareolidae (pratincoles), Todidae (todies), Psittacidae (parrots), Psittaculidae (Old World parrots), Meliphagidae (honeyeaters), Dicruridae (drongos), Monarchidae (monarchs), Pycnonotidae (bulbuls), Scotocercidae (bush warblers and allies), Zosteropidae (white-eyes), Sturnidae (starlings, except as listed in Japanese treaty), Ploceidae (weavers), Estrildidae (estrildid finches), and Passeridae (Old World sparrows, including house or English sparrow), as well as numerous other families not represented in the United States or U.S. territories.

How do the changes affect the list of birds protected by the MBTA?

The amendments (16 additions, 3 removals, and 30 name changes) affect a total of 47 species and result in a net addition of 13 species to the List of Migratory Birds Protected by the MBTA, increasing the number of species on the list from 1,093 to 1,106. Five of the 16 added species are new species that have been recognized as a result of a taxonomic split and occur in the United States or U.S. territories and were previously covered under the MBTA as members of listed species (conspecific). These amendments can be logically arranged in the following five categories:

(1) Add 11 species based on review and acceptance by the AOS (since 2019), or by other appropriate ornithological authorities, and the Service of new distributional records documenting their occurrence in the United States or U.S. territories. These species belong to families covered by at least one of the four international conventions, and all are considered to be of accidental or casual occurrence. For each species, we list the State or U.S. territory in which it has been recorded plus the relevant publication:

Chestnut-winged Cuckoo, *Clamator coromandus*—Guam (Kastner et al., 2018);

Dark-billed Cuckoo, *Coccyzus melacoryphus*—Texas and Florida (AOS 2020a);

Hooded Crane, *Grus monacha*—Alaska (AOS 2022);

Northern Giant-Petrel, *Macronectes halli*—Washington (AOS 2022);

Long-legged Buzzard, *Buteo rufinus*—Alaska (AOS 2020a);

Pallas's Gull, *Ichthyaetus ichthyaetus*—Alaska (AOS 2021);

Inca Tern, *Larosterna inca*—Hawaii (AOS 2022);

Small-billed Elaenia, *Elaenia parvirostris*—Illinois (AOS 2022);

Pallas's Grasshopper Warbler, *Helopsaltes certhiola*—Alaska (AOS 2021);

Blue-and-white Swallow, *Pygochelidon cyanoleuca*—Texas (AOS 2022); and

Naumann's Thrush, *Turdus naumanni*—Alaska (AOS 2022).

(2) Add five species because of recent taxonomic changes in which taxa formerly treated as conspecific have been determined to be distinct species (*i.e.,* a taxonomic split). Given that each of these species was formerly treated as conspecific with a listed species, these additions would not change the protective status of any of these taxa, only the names by which they are known. In each case, we reference the AOS or relevant publication supporting the change:

Mexican Duck, *Anas diazi*—formerly considered conspecific with Mallard, *Anas platyrhynchos* (AOS 2020a);

Short-billed Gull, *Larus brachyrhynchus*—formerly named Mew Gull and considered conspecific with *Larus canus,* which now has the English name of Common Gull and remains on the list based on prior occurrences of the Common Gull taxon in the United States (AOS 2021);

Puerto Rican Mango, *Anthracothorax aurulentus*—formerly considered conspecific with Antillean Mango, *Anthracothorax dominicus* (AOS 2022);

Asian Stonechat, *Saxicola maurus*—formerly considered conspecific with Stonechat, *Saxicola torquatus* (AOS 2022); and

Chihuahuan Meadowlark, *Sturnella lilianae*—formerly considered conspecific with Eastern Meadowlark, *Sturnella manga* (AOS 2022).

(3) Remove three species based on revised taxonomic treatments, either because a species is taxonomically merged with another species, either on or off the list; a species previously on the list is taxonomically split into multiple species and the new species is not known to occur within the United States or U.S. territories; or the species is considered extinct (following the classification of the AOS or, for species not covered by the AOS, the Clements Checklist or peer-reviewed literature) unless any of the following criteria apply: It is protected under the

Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; 27 U.S.T. 1087); it resembles extant species included in the list that may be affected by its removal; or its removal would create difficulties implementing the MBTA and its underlying Conventions. In each case, we reference the publication supporting these changes:

Northwestern Crow, *Corvus caurinus,* is combined with American Crow, *Corvus brachyrhynchos* (AOS 2020a);

Antillean Mango, *Anthracothorax dominicus* (AOS 2022); and

Stonechat, *Saxicola torquatus* (AOS 2022).

(4) Revise the common (English) names of eight species to conform to the most recent nomenclatural treatment as described in AOS publications 2020a, 2020b, and 2021 and Clements et al. 2011, 2019, and 2021. These revisions do not change the protective status of any of these taxa, only the names by which they are known. In each case, the update is described in the table below.

(5) Revise the scientific names of 22 species to conform to the most recent nomenclatural treatment as described in AOS publications 2020a and 2021 and Clements et al. 2016 and 2021. These revisions do not change the protective status of any of these taxa, only the names by which they are known. In each case, the update is described in the table, below.

TABLE OF NAME CHANGES, AS DESCRIBED IN CATEGORIES 4 AND 5, ABOVE

[The table is organized following AOS (2021) taxonomic order. The relevant AOS or Clements publication is provided.]

Publication source and year	Previous common name	Current common name
Clements et al. 2019	Shy Ground-Dove, *Alopecoenas stairi*	Shy Ground Dove, *Alopecoenas stairi.*
Clements et al. 2019	White-throated Ground-Dove, *Alopecoenas xanthonurus*	White-throated Ground Dove, *Alopecoenas xanthonurus.*
Clements et al. 2011	Common Moorhen, *Gallinula chloropus*	Eurasian Moorhen, *Gallinula chloropus.*
AOS 2021	Mew Gull, *Larus canus*	Common Gull, *Larus canus.*
Clements et al. 2021	Rufous Night-Heron, *Nycticorax caledonicus*	Nankeen Night-Heron, *Nycticorax caledonicus.*
AOS 2020b	McCown's Longspur, *Rhynchophanes mccownii*	Thick-billed Longspur, *Rhynchophanes mccownii.*
Publication source and year	**Previous scientific name**	**Current scientific name**
AOS 2020a	Bumblebee Hummingbird, *Atthis heloisa*	Bumblebee Hummingbird, *Selasphorus heloisa.*
AOS 2020a	Puerto Rican Emerald, *Chlorostilbon maugaeus*	Puerto Rican Emerald, *Riccordia maugaeus.*
AOS 2020a	White-eared Hummingbird, *Hylocharis leucotis*	White-eared Hummingbird, *Basilinna leucotis.*
AOS 2020a	Xantus's Hummingbird, *Hylocharis xantusii*	Xantus's Hummingbird, *Basilinna xantusii.*
AOS 2022	Violet-crowned Hummingbird, *Amazilia violiceps*	Violet-crowned Hummingbird, *Ramosomyia violiceps.*
AOS 2020a	Berylline Hummingbird, *Amazilia beryllina*	Berylline Hummingbird, *Saucerottia beryllina.*
Clements et al. 2021	Matsudaira's Storm-Petrel, *Oceanodroma matsudairae*	Matsudaira's Storm-Petrel, *Hydrobates matsudairae.*
Clements et al. 2016	Little Pied Cormorant, *Phalacrocorax melanoleucos*	Little Pied Cormorant, *Microcarbo melanoleucos.*
AOS 2021	Brandt's Cormorant, *Phalacrocorax penicillatus*	Brandt's Cormorant, *Urile penicillatus.*
AOS 2021	Red-faced Cormorant, *Phalacrocorax urile*	Red-faced Cormorant, *Urile urile.*
AOS 2021	Pelagic Cormorant, *Phalacrocorax pelagicus*	Pelagic Cormorant, *Urile pelagicus.*
AOS 2021	Double-crested Cormorant, *Phalacrocorax auritus*	Double-crested Cormorant, *Nannopterum auritum.*
AOS 2021	Neotropic Cormorant, *Phalacrocorax brasilianus*	Neotropic Cormorant, *Nannopterum brasilianum.*
AOS 2022	Mottled Owl, *Ciccaba virgata*	Mottled Owl, *Strix virgata.*
AOS 2021	Crested Caracara, *Caracara cheriway*	Crested Caracara, *Caracara plancus.*
AOS 2021	Ruby-crowned Kinglet, *Regulus calendula*	Ruby-crowned Kinglet, *Corthylio calendula.*
AOS 2021	Sedge Wren, *Cistothorus platensis*	Sedge Wren, *Cistothorus stellaris.*
AOS 2020a	Dusky Thrush, *Turdus naumanni*	Dusky Thrush, *Turdus eunomus.*
AOS 2021	Antillean Euphonia, *Euphonia musica*	Antillean Euphonia, *Chlorophonia musica.*
AOS 2021	Five-striped Sparrow, *Amphispiza quinquestriata*	Five-striped Sparrow, *Amphispizopsis quinquestriata.*
Publication source and year	**Previous common and scientific name**	**Current common and scientific name**
AOS 2020a	Puerto Rican Screech-Owl, *Megascops nudipes*	Puerto Rican Owl, *Gymnasio nudipes.*
AOS 2020a, AOS 2021	Middendorff 's Grasshopper-Warbler, *Locustella ochotensis.*	Middendorff's Grasshopper Warbler, *Helopsaltes ochotensis.*

How is the list of birds protected by the MBTA organized?

The species are listed in two formats to suit the needs of different segments of the public: alphabetically in 50 CFR 10.13(c)(1) and taxonomically in 50 CFR 10.13(c)(2). In the alphabetical listing, species are listed by common (English) group names, with the scientific name of each species following the English group name. This format is most useful to members of the lay public. In the taxonomic listing, species are listed in phylogenetic sequence by scientific name, with the English name following the scientific name. To help clarify species relationships, we also list the higher-level taxonomic categories of Order, Family, and Subfamily. This format follows the sequence adopted by the AOS (1998, 2021) and is most useful to ornithologists and other scientists.

In this rule, we present a new table format for the alphabetical and taxonomic listings at 50 CFR 10.13(c)(1) and (c)(2), respectively. We made this change in presenting these listings to conform to the Office of the Federal Register's formatting standards and to make information on the lists clearer and easier to locate. For clarity, we also added a new section heading for 50 CFR 10.13: rather than the current ''List of Migratory Birds,'' we title this section of the regulations, ''List of Birds Protected by the Migratory Bird Treaty Act.''

II. Special Double-Crested Cormorant Permit (50 CFR 21.123)

Because we are revising the scientific name for the Double-crested Cormorant on the List of Birds Protected by the MBTA at 50 CFR 10.13, as described above, we also revise the scientific name for that species (*Nannopterum auritum*) in our special permit regulations related to that species at 50 CFR 21.123. This is purely an administrative action that does not amend the purpose of, eligibility for, application procedures for, conditions of, information-collection requirements associated with, or any other regulatory provisions associated with that permit.

III. List of Endangered and Threatened Wildlife (50 CFR 17.11(h))

We also revise the corresponding entries on the List of Endangered and Threatened Wildlife of several migratory bird species that are also listed as endangered or threatened species under the ESA to reflect the currently accepted taxonomy and nomenclature. These revisions ensure consistency in the use of common and scientific names across Service regulations. Some ESA-listed migratory bird species' names are not included in this rule because they are being corrected in other documents that have published, or will publish, in the **Federal Register**.

Background

The List of Endangered and Threatened Wildlife and the List of Endangered and Threatened Plants (''the ESA Lists''), set forth in title 50 of the CFR at §§ 17.11 and 17.12, respectively, contain the names of endangered species and threatened species federally listed pursuant to the ESA.

The regulations at 50 CFR 17.11(c) and 17.12(b) direct us to use the most recently accepted scientific name of any wildlife or plant species that we have determined to be an endangered or threatened species.

Purpose

We revise the ESA List at 50 CFR 17.11(h) to reflect the scientifically accepted taxonomy and nomenclature of nine bird species listed under section 4 of the ESA. These revisions reflect the most recently accepted scientific nomenclature in accordance with 50 CFR 17.11(c).

None of the taxonomic changes to migratory bird species listed as endangered or threatened species under the ESA are regulatory in nature; they are for accuracy and clarity. These revisions do not alter species' protections or status under either the MBTA or ESA in any way. Any actions altering a species' protection or status would require a separate rulemaking action following the procedures of 50 CFR part 424.

Taxonomic Changes to the List of Endangered and Threatened Wildlife

The table below lists the taxonomic changes that reflect the revised taxonomy and nomenclature for nine bird species listed under section 4 of the ESA. These changes reflect the most recently accepted scientific nomenclature in accordance with 50 CFR 17.11(c).

TABLE OF TAXONOMIC REVISIONS TO THE ESA LIST AT § 17.11(h) REFLECTING THE CURRENT SCIENTIFICALLY ACCEPTED TAXONOMY AND NOMENCLATURE FOR THESE SPECIES

Species name as currently listed	Corrected species name
Caracara, crested, (Audubon's) [FL DPS] (*Polyborus plancus audubonii*).	Caracara, crested, (Audubon's) [FL DPS] (*Caracara plancus audubonii*).
Crane, Mississippi sandhill (*Grus canadensis pulla*)	Crane, Mississippi sandhill (*Antigone canadensis pulla*).
Nightjar, Puerto Rican (*Caprimulgus noctitherus*)	Nightjar, Puerto Rican (*Antrostomus noctitherus*).
Pigeon, Puerto Rican plain (*Columba inornata wetmorei*)	Pigeon, Puerto Rican plain (*Patagioenas inornata wetmorei*).
Rail, California clapper (*Rallus longirostris obsoletus*)	Rail, California Ridgway's (*Rallus obsoletus obsoletus*).
Rail, light-footed clapper (*Rallus longirostris levipes*)	Rail, light-footed Ridgway's (*Rallus obsoletus levipes*).
Sparrow, Cape Sable seaside (*Ammodramus maritimus mirabilis*)	Sparrow, Cape Sable seaside (*Ammospiza maritima mirabilis*).
Tern, California least (*Sterna antillarum browni*)	Tern, California least (*Sternula antillarum browni*).
Towhee, Inyo California (*Pipilo crissalis eremophilus*)	Towhee, Inyo California (*Melozone crissalis eremophilus*).

Using the best available scientific information, this rule documents taxonomic changes of the scientific names for nine birds in their entries on the ESA List. To the extent practicable, the Service relies on the Integrated Taxonomic Information System (ITIS) to determine a species' scientific name for inclusion on the List. ITIS incorporates the naming principles established by the International Code of Zoological Nomenclature, produced by the International Commission on Zoological Nomenclature, an organization that provides and regulates a uniform system of zoological nomenclature. While ITIS is a reliable database source of taxonomic information, ITIS is incomplete and does not yet reflect the most recently accepted scientific names for some species. As noted above, the scientific names for the nine listed bird species are supported by AOS's Checklist of North American birds (AOU 1998), as amended annually (AOU 2006, 2010, 2012, 2014, 2016; AOS 2018, 2020a, 2020b, and 2021). The Service finds that the scientific and common names should be recognized as presented in the table above. Accordingly, we revise the scientific names of these species under section 4 of the ESA and in accordance with 50 CFR 17.11(c).

Of the nine species that are subject to the taxonomic revisions of the ESA List in this rule, three have designated critical habitat. For clarity and consistency, we revise the headings of the critical habitat designations at 50 CFR 17.95(b) to reflect the corrected scientific names for the following species: Mississippi sandhill crane, Cape Sable seaside sparrow, and Inyo California towhee.

These changes do not affect the range or endangered or threatened status for any of these nine listed migratory bird species, or any designated critical habitat.

IV. Summary of Comments and Responses

On December 12, 2022, we published in the **Federal Register** (87 FR 75977) a proposed rule to revise the list of migratory birds at 50 CFR 10.13; we accepted public comments on the proposed rule for 60 days, ending February 10, 2023. We received seven comments in response to the proposed rule; five were from private individuals, one was from a State Game and Fish Department, and one was from an organization. Several comments supported the changes we proposed. The following text discusses the

substantive comments we received by topic and provides our responses.

Comment (1): One individual requested that no species be removed from protection.

Response: As explained above, species are removed from the list of migratory birds at 50 CFR 10.13 based on revised taxonomic treatments, either because a species is taxonomically merged with another species, either on or off the list; a species previously on the list is taxonomically split into multiple species and the new species is not known to occur within the United States or U.S. territories; or the species is considered extinct (following the classification of the AOS or, for species not covered by the AOS, the Clements Checklist or peer-reviewed literature) unless any of the following criteria apply: It is protected under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), or the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES; 27 U.S.T. 1087); it resembles extant species included in the list that may be affected by its removal; or its removal would create difficulties implementing the MBTA and its underlying Conventions. We are removing three species from the list that fit one or more of these criteria.

Comment (2): One individual requested that Ainley's Storm-Petrel (*Hydrobates cheimomnestes*) be added to the list of migratory birds at 50 CFR 10.13 because there is published evidence of its occurrence in waters off California and provided a weblink for the publication.

Response: We reviewed the published evidence for the occurrence of Ainley's Storm-Petrel. In summary, the published evidence is for a scientific study where Ainley's Storm-Petrels breeding on an islet in Mexico were tagged with Global Positioning System data loggers and the tracks of multiple birds showed birds flew into U.S. waters off the coast of southern California. As described above, we primarily rely on the expertise of the AOS Committee on Classification and Nomenclature to compile the distributional information for each species on the AOS Checklist, including whether the species is known to occur in the United States. We then evaluate available documentation for any species added based on new natural distribution in the United States and come to our own conclusion about adding it to the list. The AOS Committee has not yet published a decision on these potential occurrences of Ainley's Storm-Petrel in the United States and has not yet addressed the occurrence of any species established only by the presence of birds tagged with GPS-data loggers. We will evaluate whether to add the species to the list after the AOS Committee or other ornithological experts have assessed the evidence for occurrence of Ainley's Storm-Petrel in U.S. waters based solely on remote-sensing technology.

Comment (3): One commenter made the comment that the Service is unlawfully applying the MBTA by misinterpreting the plain language meaning of the term ''occurring.''

Response: The Service's interpretation of the term ''occurring'' is a reasonable reading of the MBTA, which protects species ''native to the United States or its territories'' and defines that phrase to mean ''occurring in the United States or its territories as the result of natural biological or ecological processes'' (16 U.S.C. 703(b)(2)). This definition demonstrates that the word ''occurring'' refers to the species protected by the statute. ''Species'' is a collective noun that refers to a group of individual birds—in other words, a ''species'' occurs wherever there is an individual member of the species. Therefore, the MBTA encompasses every bird species covered by the treaties for which there has been at least one occurrence in the United States or its territories as the result of natural processes. Moreover, nothing in the statute's legislative history suggests that Congress was concerned with the number of records documenting a species' natural occurrence in the United States or U.S. territories. There is also no established or accepted scientific process to determine a species is occurring in the United States or U.S. territories based on an undefined threshold number of documented records. Thus, a single documented, reviewed, and accepted record of natural occurrence in the United States or U.S. territories is not only a reasonable threshold to qualify a species for protection under the MBTA but is the threshold compelled by the plain language of the statute.

V. Summary of Changes From the Proposed Rule

As noted above under IV. Summary of Comments and Responses, in this final rule, we do not make any substantive changes to our December 12, 2022, proposed rule (87 FR 75977) in response to comments we received during that proposal's comment period. Further, we did not receive any new information that led us to make any substantive changes to our proposed rule in this final rule. The only changes we have made to the proposed rule in this final rule are minor editorial revisions to correct spellings or to ensure clarity and consistency in the formatting and presentation of the rule.

VI. Required Determinations

Regulatory Planning and Review (Executive Orders 12866 and 13563)

Executive Order (E.O.) 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

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

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

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (5 U.S.C. 804(2)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule does not have a significant economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide the statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities. We have examined this rule's potential effects on small entities as required by the Regulatory Flexibility Act and have determined that this action will not have a significant economic impact on a substantial number of small entities. This rule is an

administrative action to update the list of migratory bird species protected under the Conventions and make certain corresponding updates on the ESA List. Because of the administrative nature of this rulemaking, the final rule will have no known economic impacts on small entities. Consequently, we certify that this rule will not have a significant economic impact on a substantial number of small entities; therefore, a regulatory flexibility analysis is not required.

Congressional Review Act

This rule is not a major rule under 5 U.S.C. 804(2), the Congressional Review Act. It will not have a significant impact on a substantial number of small entities.

a. This rule will not have an annual effect on the economy of $100 million or more.

b. This rule will not cause a major increase in costs or prices for consumers; individual industries; Federal, State, or local government agencies; or geographic regions.

c. This rule will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

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

a. This rule does not ''significantly or uniquely'' affect small governments. A small government agency plan is not required. This rule is an administrative action to update the list of migratory bird species protected under the Conventions and make certain corresponding updates on the ESA List; it does not affect small government activities in any significant way.

b. This rule does not produce a federal mandate of $100 million or greater in any year; *i.e.,* it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

In accordance with Executive Order 12630, this rule does not have significant takings implications. This rule does not contain a provision for the taking of private property. Therefore, a takings-implication assessment is not required.

Federalism

This rule does not have sufficient Federalism effects to warrant preparation of a federalism summary impact statement under Executive Order 13132. It does not interfere with the States' ability to manage themselves or their funds. No significant economic impacts are expected to result from updating the list of migratory bird species and certain entries on the ESA List.

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. 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.

National Environmental Policy Act (NEPA)

Given that the revisions in this document are strictly administrative in nature, this action is categorically excluded from further NEPA requirements (see 43 CFR 46.210(i), applying to policies, directives, regulations, and guidelines that are of an administrative, financial, legal, technical, or procedural nature).

Endangered Species Act (ESA)

Of the species on the List of Birds Protected by the Migratory Bird Treaty Act, 89 species, subspecies, or distinct population segments are also listed as endangered or threatened under section 4 of the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*). No legal complications arise from the dual listing as the two lists are developed under separate authorities for different purposes. Because this rule is strictly administrative in nature, it has no effect on endangered or threatened species or their designated critical habitats. Thus, it does not require consultation under section 7 of the ESA.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated potential effects on federally recognized Indian Tribes and have determined that there are no potential effects. The revisions to existing regulations in this rule are purely administrative in nature and do not interfere with or affect the Tribes' ability to manage themselves or their funds or to regulate migratory bird activities on Tribal lands.

Energy Supply, Distribution, or Use (Executive Order 13211)

On May 18, 2001, the President issued Executive Order 13211 addressing regulations that significantly affect energy supply, distribution, or use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this rule is an administrative action to update the list of migratory bird species protected under the Conventions and make certain corresponding updates on the ESA List, it is not a significant regulatory action under Executive Order 12866, and it does not significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

References Cited

A complete list of all references cited is available on *https://www.regulations.gov* under Docket No. FWS–HQ–MB–2022–0036, and upon request (see **FOR FURTHER INFORMATION CONTACT**, above).

List of Subjects

CFR Part 10

Exports, Fish, Imports, Law enforcement, Plants, Transportation, Wildlife.

CFR Part 17

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

CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

Regulation Promulgation

For the reasons discussed in the preamble, we amend title 50, chapter I, subchapter B of the Code of Federal Regulations, as follows:

PART 10—GENERAL PROVISIONS

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

Authority: 16 U.S.C. 668a–d, 703–712, 742a–j–l, 1361–1384, 1401–1407, 1531–1543, 3371–3378; 18 U.S.C. 42; 19 U.S.C. 1202.

■ 2. Amend § 10.13 by revising the section heading and paragraph (c) to read as follows:

§ 10.13 List of Birds Protected by the Migratory Bird Treaty Act.

* * * * *

(c) *What species are protected by the Migratory Bird Treaty Act?* Species protected as migratory birds are listed in two formats to suit the varying needs of the user: Alphabetically in paragraph (c)(1) of this section and taxonomically in paragraph (c)(2) of this section. Taxonomy and nomenclature generally follow the 7th edition of the American Ornithologists' Union's (AOU, now recognized as American Ornithological Society (AOS)) *Checklist of North American birds* (1998, as amended through 2021). For species not treated by the AOS *Checklist,* we generally follow *Clements Checklist of Birds of the World* (Clements et al. 2007, as updated through 2021).

(1) *Alphabetical listing.* The table lists species alphabetically by common (English) group names, with the scientific name of each species following the common name.

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT

Common name group	Species common name	Species scientific name
Accentor	Siberian Accentor	*Prunella montanella.*
‘Akeke‘e	‘Akeke‘e	*Loxops caeruleirostris.*
‘Akepa	Hawaii ‘Akepa	*Loxops coccineus.*
	Maui ‘Akepa	*Loxops ochraceus.*
	O‘ahu ‘Akepa	*Loxops wolstenholmei.*
‘Akialoa	Kauai ‘Akialoa	*Akialoa stejnegeri.*
	Maui Nui ’Akialoa	*Akialoa lanaiensis.*
	O‘ahu ‘Akialoa	*Akialoa ellisiana.*
‘Akiapola‘au	‘Akiapola‘au	*Hemignathus wilsoni.*
‘Akikiki	‘Akikiki	*Oreomystis bairdi.*
‘Akohekohe	‘Akohekohe	*Palmeria dolei.*
‘Alauahio	Maui ‘Alauahio	*Paroreomyza montana.*
	O‘ahu ‘Alauahio	*Paroreomyza maculata.*
Albatross	Black-browed Albatross	*Thalassarche melanophris.*
	Black-footed Albatross	*Phoebastria nigripes.*
	Chatham Albatross	*Thalassarche eremita.*
	Laysan Albatross	*Phoebastria immutabilis.*
	Light-mantled Albatross	*Phoebetria palpebrata.*
	Salvin's Albatross	*Thalassarche salvini.*
	Short-tailed Albatross	*Phoebastria albatrus.*
	Wandering Albatross	*Diomedea exulans.*
	White-capped Albatross	*Thalassarche cauta.*
	Yellow-nosed Albatross	*Thalassarche chlororhynchos.*
‘Amakihi	Hawaii ‘Amakihi	*Chlorodrepanis virens.*
	Kaua‘i ‘Amakihi	*Chlorodrepanis stejnegeri.*
	O‘ahu ‘Amakihi	*Chlorodrepanis flava.*
Anhinga	Anhinga	*Anhinga anhinga.*
Ani	Groove-billed Ani	*Crotophaga sulcirostris.*
	Smooth-billed Ani	*Crotophaga ani.*
‘Anianiau	‘Anianiau	*Magumma parva.*
‘Apapane	‘Apapane	*Himatione sanguinea.*
Auklet	Cassin's Auklet	*Ptychoramphus aleuticus.*
	Crested Auklet	*Aethia cristatella.*
	Least Auklet	*Aethia pusilla.*
	Parakeet Auklet	*Aethia psittacula.*
	Rhinoceros Auklet	*Cerorhinca monocerata.*
	Whiskered Auklet	*Aethia pygmaea.*
Avocet	American Avocet	*Recurvirostra americana.*
Bananaquit	Bananaquit	*Coereba flaveola.*
Bean-Goose	Taiga Bean-Goose	*Anser fabalis.*
	Tundra Bean-Goose	*Anser serrirostris.*
Beardless-Tyrannulet	Northern Beardless-Tyrannulet	*Camptostoma imberbe.*
Becard	Gray-collared Becard	*Pachyramphus major.*
	Rose-throated Becard	*Pachyramphus aglaiae.*
Bittern	American Bittern	*Botaurus lentiginosus.*
	Black Bittern	*Ixobrychus flavicollis.*
	Least Bittern	*Ixobrychus exilis.*
	Schrenck's Bittern	*Ixobrychus eurhythmus.*
	Yellow Bittern	*Ixobrychus sinensis.*
Blackbird	Brewer's Blackbird	*Euphagus cyanocephalus.*
	Red-winged Blackbird	*Agelaius phoeniceus.*
	Rusty Blackbird	*Euphagus carolinus.*
	Tawny-shouldered Blackbird	*Agelaius humeralis.*
	Tricolored Blackbird	*Agelaius tricolor.*
	Yellow-headed Blackbird	*Xanthocephalus xanthocephalus.*
	Yellow-shouldered Blackbird	*Agelaius xanthomus.*
Bluebird	Eastern Bluebird	*Sialia sialis.*
	Mountain Bluebird	*Sialia currucoides.*
	Western Bluebird	*Sialia mexicana.*
Bluetail	Red-flanked Bluetail	*Tarsiger cyanurus.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Bluethroat	Bluethroat	*Cyanecula svecica.*
Bobolink	Bobolink	*Dolichonyx oryzivorus.*
Boobook	Northern Boobook	*Ninox japonica.*
Booby	Abbott's Booby	*Papasula abbotti.*
	Blue-footed Booby	*Sula nebouxii.*
	Brown Booby	*Sula leucogaster.*
	Masked Booby	*Sula dactylatra.*
	Nazca Booby	*Sula granti.*
	Red-footed Booby	*Sula sula.*
Brambling	Brambling	*Fringilla montifringilla.*
Brant	Brant	*Branta bernicla.*
Bufflehead	Bufflehead	*Bucephala albeola.*
Bullfinch	Eurasian Bullfinch	*Pyrrhula pyrrhula.*
	Puerto Rican Bullfinch	*Melopyrrha portoricensis.*
Bunting	Blue Bunting	*Cyanocompsa parellina.*
	Gray Bunting	*Emberiza variabilis.*
	Indigo Bunting	*Passerina cyanea.*
	Lark Bunting	*Calamospiza melanocorys.*
	Lazuli Bunting	*Passerina amoena.*
	Little Bunting	*Emberiza pusilla.*
	McKay's Bunting	*Plectrophenax hyperboreus.*
	Painted Bunting	*Passerina ciris.*
	Pallas's Bunting	*Emberiza pallasi.*
	Pine Bunting	*Emberiza leucocephalos.*
	Reed Bunting	*Emberiza schoeniclus.*
	Rustic Bunting	*Emberiza rustica.*
	Snow Bunting	*Plectrophenax nivalis.*
	Varied Bunting	*Passerina versicolor.*
	Yellow-breasted Bunting	*Emberiza aureola.*
	Yellow-browed Bunting	*Emberiza chrysophrys.*
	Yellow-throated Bunting	*Emberiza elegans.*
Bushtit	Bushtit	*Psaltriparus minimus.*
Buzzard	Gray-faced Buzzard	*Butastur indicus.*
	Long-legged Buzzard	*Buteo rufinus.*
Canvasback	Canvasback	*Aythya valisineria.*
Caracara	Crested Caracara	*Caracara plancus.*
Cardinal	Northern Cardinal	*Cardinalis cardinalis.*
Carib	Green-throated Carib	*Eulampis holosericeus.*
	Purple-throated Carib	*Eulampis jugularis.*
Catbird	Black Catbird	*Melanoptila glabrirostris.*
	Gray Catbird	*Dumetella carolinensis.*
Chaffinch	Common Chaffinch	*Fringilla coelebs.*
Chat	Yellow-breasted Chat	*Icteria virens.*
Chickadee	Black-capped Chickadee	*Poecile atricapillus.*
	Boreal Chickadee	*Poecile hudsonicus.*
	Carolina Chickadee	*Poecile carolinensis.*
	Chestnut-backed Chickadee	*Poecile rufescens.*
	Gray-headed Chickadee	*Poecile cinctus.*
	Mexican Chickadee	*Poecile sclateri.*
	Mountain Chickadee	*Poecile gambeli.*
Chiffchaff	Common Chiffchaff	*Phylloscopus collybita.*
Chuck-will's-widow	Chuck-will's-widow	*Antrostomus carolinensis.*
Condor	California Condor	*Gymnogyps californianus.*
Coot	American Coot	*Fulica americana.*
	Eurasian Coot	*Fulica atra.*
	Hawaiian Coot	*Fulica alai.*
Cormorant	Brandt's Cormorant	*Urile penicillatus.*
	Double-crested Cormorant	*Nannopterum auritum.*
	Great Cormorant	*Phalacrocorax carbo.*
	Little Pied Cormorant	*Microcarbo melanoleucos.*
	Neotropic Cormorant	*Nannopterum brasilianum.*
	Pelagic Cormorant	*Urile pelagicus.*
	Red-faced Cormorant	*Urile urile.*
Cowbird	Bronzed Cowbird	*Molothrus aeneus.*
	Brown-headed Cowbird	*Molothrus ater.*
	Shiny Cowbird	*Molothrus bonariensis.*
Crake	Corn Crake	*Crex crex.*
	Paint-billed Crake	*Neocrex erythrops.*
	Spotless Crake	*Porzana tabuensis.*
	Yellow-breasted Crake	*Hapalocrex flaviventer.*
Crane	Common Crane	*Grus grus.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Hooded Crane	*Grus monacha.*
	Sandhill Crane	*Antigone canadensis.*
	Whooping Crane	*Grus americana.*
Creeper	Brown Creeper	*Certhia americana.*
	Hawaii Creeper	*Loxops mana.*
Crossbill	Cassia Crossbill	*Loxia sinesciuris.*
	Red Crossbill	*Loxia curvirostra.*
	White-winged Crossbill	*Loxia leucoptera.*
Crow	American Crow	*Corvus brachyrhynchos.*
	Fish Crow	*Corvus ossifragus.*
	Hawaiian Crow	*Corvus hawaiiensis.*
	Mariana Crow	*Corvus kubaryi.*
	Tamaulipas Crow	*Corvus imparatus.*
	White-necked Crow	*Corvus leucognaphalus.*
Cuckoo	Black-billed Cuckoo	*Coccyzus erythropthalmus.*
	Chestnut-winged Cuckoo	*Clamator coromandus.*
	Common Cuckoo	*Cuculus canorus.*
	Dark-billed Cuckoo	*Coccyzus melacoryphus.*
	Mangrove Cuckoo	*Coccyzus minor.*
	Oriental Cuckoo	*Cuculus optatus.*
	Yellow-billed Cuckoo	*Coccyzus americanus.*
Curlew	Bristle-thighed Curlew	*Numenius tahitiensis.*
	Eskimo Curlew	*Numenius borealis.*
	Eurasian Curlew	*Numenius arquata.*
	Far Eastern Curlew	*Numenius madagascariensis.*
	Little Curlew	*Numenius minutus.*
	Long-billed Curlew	*Numenius americanus.*
Dickcissel	Dickcissel	*Spiza americana.*
Dipper	American Dipper	*Cinclus mexicanus.*
Dotterel	Eurasian Dotterel	*Charadrius morinellus.*
Dove	Common Ground Dove	*Columbina passerina.*
	Inca Dove	*Columbina inca.*
	Mourning Dove	*Zenaida macroura.*
	Ruddy Ground Dove	*Columbina talpacoti.*
	Shy Ground Dove	*Alopecoenas stairi.*
	White-throated Ground Dove	*Alopecoenas xanthonurus.*
	White-tipped Dove	*Leptotila verreauxi.*
	White-winged Dove	*Zenaida asiatica.*
	Zenaida Dove	*Zenaida aurita.*
Dovekie	Dovekie	*Alle alle.*
Dowitcher	Long-billed Dowitcher	*Limnodromus scolopaceus.*
	Short-billed Dowitcher	*Limnodromus griseus.*
Duck	American Black Duck	*Anas rubripes.*
	Eastern Spot-billed Duck	*Anas zonorhyncha.*
	Falcated Duck	*Mareca falcata.*
	Harlequin Duck	*Histrionicus histrionicus.*
	Hawaiian Duck	*Anas wyvilliana.*
	Laysan Duck	*Anas laysanensis.*
	Long-tailed Duck	*Clangula hyemalis.*
	Masked Duck	*Nomonyx dominicus.*
	Mexican Duck	*Anas diazi.*
	Mottled Duck	*Anas fulvigula.*
	Muscovy Duck	*Cairina moschata.*
	Pacific Black Duck	*Anas superciliosa.*
	Ring-necked Duck	*Aythya collaris.*
	Ruddy Duck	*Oxyura jamaicensis.*
	Tufted Duck	*Aythya fuligula.*
	Wood Duck	*Aix sponsa.*
Dunlin	Dunlin	*Calidris alpina.*
Eagle	Bald Eagle	*Haliaeetus leucocephalus.*
	Golden Eagle	*Aquila chrysaetos.*
	White-tailed Eagle	*Haliaeetus albicilla.*
Egret	Cattle Egret	*Bubulcus ibis.*
	Chinese Egret	*Egretta eulophotes.*
	Great Egret	*Ardea alba.*
	Intermediate Egret	*Ardea intermedia.*
	Little Egret	*Egretta garzetta.*
	Reddish Egret	*Egretta rufescens.*
	Snowy Egret	*Egretta thula.*
Eider	Common Eider	*Somateria mollissima.*
	King Eider	*Somateria spectabilis.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Spectacled Eider	*Somateria fischeri.*
	Steller's Eider	*Polysticta stelleri.*
Elaenia	Caribbean Elaenia	*Elaenia martinica.*
	Greenish Elaenia	*Myiopagis viridicata.*
	Small-billed Elaenia	*Elaenia parvirostris.*
	White-crested Elaenia	*Elaenia albiceps.*
Emerald	Puerto Rican Emerald	*Riccordia maugaeus.*
Euphonia	Antillean Euphonia	*Chlorophonia musica.*
Falcon	Amur Falcon	*Falco amurensis.*
	Aplomado Falcon	*Falco femoralis.*
	Peregrine Falcon	*Falco peregrinus.*
	Prairie Falcon	*Falco mexicanus.*
	Red-footed Falcon	*Falco vespertinus.*
Fieldfare	Fieldfare	*Turdus pilaris.*
Finch	Cassin's Finch	*Haemorhous cassinii.*
	House Finch	*Haemorhous mexicanus.*
	Laysan Finch	*Telespiza cantans.*
	Nihoa Finch	*Telespiza ultima.*
	Purple Finch	*Haemorhous purpureus.*
Flamingo	American Flamingo	*Phoenicopterus ruber.*
Flicker	Gilded Flicker	*Colaptes chrysoides.*
	Northern Flicker	*Colaptes auratus.*
Flycatcher	Acadian Flycatcher	*Empidonax virescens.*
	Alder Flycatcher	*Empidonax alnorum.*
	Ash-throated Flycatcher	*Myiarchus cinerascens.*
	Asian Brown Flycatcher	*Muscicapa dauurica.*
	Brown-crested Flycatcher	*Myiarchus tyrannulus.*
	Buff-breasted Flycatcher	*Empidonax fulvifrons.*
	Cordilleran Flycatcher	*Empidonax occidentalis.*
	Crowned Slaty Flycatcher	*Empidonomus aurantioatrocristatus.*
	Dark-sided Flycatcher	*Muscicapa sibirica.*
	Dusky Flycatcher	*Empidonax oberholseri.*
	Dusky-capped Flycatcher	*Myiarchus tuberculifer.*
	Fork-tailed Flycatcher	*Tyrannus savana.*
	Gray Flycatcher	*Empidonax wrightii.*
	Gray-streaked Flycatcher	*Muscicapa griseisticta.*
	Great Crested Flycatcher	*Myiarchus crinitus.*
	Hammond's Flycatcher	*Empidonax hammondii.*
	La Sagra's Flycatcher	*Myiarchus sagrae.*
	Least Flycatcher	*Empidonax minimus.*
	Mugimaki Flycatcher	*Ficedula mugimaki.*
	Narcissus Flycatcher	*Ficedula narcissina.*
	Nutting's Flycatcher	*Myiarchus nuttingi.*
	Olive-sided Flycatcher	*Contopus cooperi.*
	Pacific-slope Flycatcher	*Empidonax difficilis.*
	Pine Flycatcher	*Empidonax affinis.*
	Piratic Flycatcher	*Legatus leucophaius.*
	Puerto Rican Flycatcher	*Myiarchus antillarum.*
	Scissor-tailed Flycatcher	*Tyrannus forficatus.*
	Social Flycatcher	*Myiozetetes similis.*
	Spotted Flycatcher	*Muscicapa striata.*
	Sulphur-bellied Flycatcher	*Myiodynastes luteiventris.*
	Taiga Flycatcher	*Ficedula albicilla.*
	Tufted Flycatcher	*Mitrephanes phaeocercus.*
	Variegated Flycatcher	*Empidonomus varius.*
	Vermilion Flycatcher	*Pyrocephalus rubinus.*
	Willow Flycatcher	*Empidonax traillii.*
	Yellow-bellied Flycatcher	*Empidonax flaviventris.*
Forest-Falcon	Collared Forest-Falcon	*Micrastur semitorquatus.*
Frigatebird	Great Frigatebird	*Fregata minor.*
	Lesser Frigatebird	*Fregata ariel.*
	Magnificent Frigatebird	*Fregata magnificens.*
Fruit-Dove	Crimson-crowned Fruit-Dove	*Ptilinopus porphyraceus.*
	Many-colored Fruit-Dove	*Ptilinopus perousii.*
	Mariana Fruit-Dove	*Ptilinopus roseicapilla.*
Fulmar	Northern Fulmar	*Fulmarus glacialis.*
Gadwall	Gadwall	*Mareca strepera.*
Gallinule	Azure Gallinule	*Porphyrio flavirostris.*
	Common Gallinule	*Gallinula galeata.*
	Purple Gallinule	*Porphyrio martinicus.*
Gannet	Northern Gannet	*Morus bassanus.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Garganey	Garganey	*Spatula querquedula.*
Giant-Petrel	Northern Giant-Petrel	*Macronectes halli.*
Gnatcatcher	Black-capped Gnatcatcher	*Polioptila nigriceps.*
	Black-tailed Gnatcatcher	*Polioptila melanura.*
	Blue-Gray Gnatcatcher	*Polioptila caerulea.*
	California Gnatcatcher	*Polioptila californica.*
Godwit	Bar-tailed Godwit	*Limosa lapponica.*
	Black-tailed Godwit	*Limosa limosa.*
	Hudsonian Godwit	*Limosa haemastica.*
	Marbled Godwit	*Limosa fedoa.*
Goldeneye	Barrow's Goldeneye	*Bucephala islandica.*
	Common Goldeneye	*Bucephala clangula.*
Golden-Plover	American Golden-Plover	*Pluvialis dominica.*
	European Golden-Plover	*Pluvialis apricaria.*
	Pacific Golden-Plover	*Pluvialis fulva.*
Goldfinch	American Goldfinch	*Spinus tristis.*
	Lawrence's Goldfinch	*Spinus lawrencei.*
	Lesser Goldfinch	*Spinus psaltria.*
Goose	Barnacle Goose	*Branta leucopsis.*
	Cackling Goose	*Branta hutchinsii.*
	Canada Goose	*Branta canadensis.*
	Emperor Goose	*Anser canagicus.*
	Greater White-fronted Goose	*Anser albifrons.*
	Hawaiian Goose	*Branta sandvicensis.*
	Lesser White-fronted Goose	*Anser erythropus.*
	Pink-footed Goose	*Anser brachyrhynchus.*
	Ross's Goose	*Anser rossii.*
	Snow Goose	*Anser caerulescens.*
Goshawk	Northern Goshawk	*Accipiter gentilis.*
Grackle	Boat-tailed Grackle	*Quiscalus major.*
	Common Grackle	*Quiscalus quiscula.*
	Greater Antillean Grackle	*Quiscalus niger.*
	Great-tailed Grackle	*Quiscalus mexicanus.*
Grassquit	Black-faced Grassquit	*Melanospiza bicolor.*
	Yellow-faced Grassquit	*Tiaris olivaceus.*
Grebe	Clark's Grebe	*Aechmophorus clarkii.*
	Eared Grebe	*Podiceps nigricollis.*
	Horned Grebe	*Podiceps auritus.*
	Least Grebe	*Tachybaptus dominicus.*
	Pied-billed Grebe	*Podilymbus podiceps.*
	Red-necked Grebe	*Podiceps grisegena.*
	Western Grebe	*Aechmophorus occidentalis.*
Greenfinch	Oriental Greenfinch	*Chloris sinica.*
Greenshank	Common Greenshank	*Tringa nebularia.*
	Nordmann's Greenshank	*Tringa guttifer.*
Grosbeak	Black-headed Grosbeak	*Pheucticus melanocephalus.*
	Blue Grosbeak	*Passerina caerulea.*
	Crimson-collared Grosbeak	*Rhodothraupis celaeno.*
	Evening Grosbeak	*Coccothraustes vespertinus.*
	Pine Grosbeak	*Pinicola enucleator.*
	Rose-breasted Grosbeak	*Pheucticus ludovicianus.*
	Yellow Grosbeak	*Pheucticus chrysopeplus.*
Guillemot	Black Guillemot	*Cepphus grylle.*
	Pigeon Guillemot	*Cepphus columba.*
Gull	Belcher's Gull	*Larus belcheri.*
	Black-headed Gull	*Chroicocephalus ridibundus.*
	Black-tailed Gull	*Larus crassirostris.*
	Bonaparte's Gull	*Chroicocephalus philadelphia.*
	California Gull	*Larus californicus.*
	Common Gull	*Larus canus.*
	Franklin's Gull	*Leucophaeus pipixcan.*
	Glaucous Gull	*Larus hyperboreus.*
	Glaucous-winged Gull	*Larus glaucescens.*
	Gray-hooded Gull	*Chroicocephalus cirrocephalus.*
	Great Black-backed Gull	*Larus marinus.*
	Heermann's Gull	*Larus heermanni.*
	Herring Gull	*Larus argentatus.*
	Iceland Gull	*Larus glaucoides.*
	Ivory Gull	*Pagophila eburnea.*
	Kelp Gull	*Larus dominicanus.*
	Laughing Gull	*Leucophaeus atricilla.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Lesser Black-backed Gull	*Larus fuscus.*
	Little Gull	*Hydrocoloeus minutus.*
	Pallas's Gull	*Ichthyaetus ichthyaetus.*
	Ring-billed Gull	*Larus delawarensis.*
	Ross's Gull	*Rhodostethia rosea.*
	Sabine's Gull	*Xema sabini.*
	Short-billed Gull	*Larus brachyrhynchus.*
	Slaty-backed Gull	*Larus schistisagus.*
	Swallow-tailed Gull	*Creagrus furcatus.*
	Western Gull	*Larus occidentalis.*
	Yellow-footed Gull	*Larus livens.*
	Yellow-legged Gull	*Larus michahellis.*
Gyrfalcon	Gyrfalcon	*Falco rusticolus.*
Harrier	Northern Harrier	*Circus hudsonius.*
Hawfinch	Hawfinch	*Coccothraustes coccothraustes.*
Hawk	Broad-winged Hawk	*Buteo platypterus.*
	Common Black Hawk	*Buteogallus anthracinus.*
	Cooper's Hawk	*Accipiter cooperii.*
	Crane Hawk	*Geranospiza caerulescens.*
	Ferruginous Hawk	*Buteo regalis.*
	Gray Hawk	*Buteo plagiatus.*
	Great Black Hawk	*Buteogallus urubitinga.*
	Harris's Hawk	*Parabuteo unicinctus.*
	Hawaiian Hawk	*Buteo solitarius.*
	Red-shouldered Hawk	*Buteo lineatus.*
	Red-tailed Hawk	*Buteo jamaicensis.*
	Roadside Hawk	*Rupornis magnirostris.*
	Rough-legged Hawk	*Buteo lagopus.*
	Sharp-shinned Hawk	*Accipiter striatus.*
	Short-tailed Hawk	*Buteo brachyurus.*
	Swainson's Hawk	*Buteo swainsoni.*
	White-tailed Hawk	*Geranoaetus albicaudatus.*
	Zone-tailed Hawk	*Buteo albonotatus.*
Hawk-Cuckoo	Hodgson's Hawk-Cuckoo	*Hierococcyx nisicolor.*
Heron	Gray Heron	*Ardea cinerea.*
	Great Blue Heron	*Ardea herodias.*
	Green Heron	*Butorides virescens.*
	Little Blue Heron	*Egretta caerulea.*
	Tricolored Heron	*Egretta tricolor.*
Hobby	Eurasian Hobby	*Falco subbuteo.*
Honeycreeper	Laysan Honeycreeper	*Himatione fraithii.*
	Red-legged Honeycreeper	*Cyanerpes cyaneus.*
Hoopoe	Eurasian Hoopoe	*Upupa epops.*
House-Martin	Common House-Martin	*Delichon urbicum.*
Hummingbird	Allen's Hummingbird	*Selasphorus sasin.*
	Anna's Hummingbird	*Calypte anna.*
	Antillean Crested Hummingbird	*Orthorhyncus cristatus.*
	Berylline Hummingbird	*Saucerottia beryllina.*
	Black-chinned Hummingbird	*Archilochus alexandri.*
	Broad-billed Hummingbird	*Cynanthus latirostris.*
	Broad-tailed Hummingbird	*Selasphorus platycercus.*
	Buff-bellied Hummingbird	*Amazilia yucatanensis.*
	Bumblebee Hummingbird	*Selasphorus heloisa.*
	Calliope Hummingbird	*Selasphorus calliope.*
	Cinnamon Hummingbird	*Amazilia rutila.*
	Costa's Hummingbird	*Calypte costae.*
	Lucifer Hummingbird	*Calothorax lucifer.*
	Rivoli's Hummingbird	*Eugenes fulgens.*
	Ruby-throated Hummingbird	*Archilochus colubris.*
	Rufous Hummingbird	*Selasphorus rufus.*
	Vervain Hummingbird	*Mellisuga minima.*
	Violet-crowned Hummingbird	*Ramosomyia violiceps.*
	White-eared Hummingbird	*Basilinna leucotis.*
	Xantus's Hummingbird	*Basilinna xantusii.*
Ibis	Glossy Ibis	*Plegadis falcinellus.*
	Scarlet Ibis	*Eudocimus ruber.*
	White Ibis	*Eudocimus albus.*
	White-faced Ibis	*Plegadis chihi.*
'I'iwi	'I'iwi	*Drepanis coccinea.*
Imperial-Pigeon	Pacific Imperial-Pigeon	*Ducula pacifica.*
Jabiru	Jabiru	*Jabiru mycteria.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Jacana	Northern Jacana	*Jacana spinosa.*
Jackdaw	Eurasian Jackdaw	*Corvus monedula.*
Jaeger	Long-tailed Jaeger	*Stercorarius longicaudus.*
	Parasitic Jaeger	*Stercorarius parasiticus.*
	Pomarine Jaeger	*Stercorarius pomarinus.*
Jay	Blue Jay	*Cyanocitta cristata.*
	Brown Jay	*Psilorhinus morio.*
	Canada Jay	*Perisoreus canadensis.*
	Green Jay	*Cyanocorax yncas.*
	Mexican Jay	*Aphelocoma wollweberi.*
	Pinyon Jay	*Gymnorhinus cyanocephalus.*
	Steller's Jay	*Cyanocitta stelleri.*
Junco	Dark-eyed Junco	*Junco hyemalis.*
	Yellow-eyed Junco	*Junco phaeonotus.*
Kākāwahie	Kākāwahie	*Paroreomyza flammea.*
Kāma'o	Kāma'o	*Myadestes myadestinus.*
Kestrel	American Kestrel	*Falco sparverius.*
	Eurasian Kestrel	*Falco tinnunculus.*
Killdeer	Killdeer	*Charadrius vociferus.*
Kingbird	Cassin's Kingbird	*Tyrannus vociferans.*
	Couch's Kingbird	*Tyrannus couchii.*
	Eastern Kingbird	*Tyrannus tyrannus.*
	Gray Kingbird	*Tyrannus dominicensis.*
	Loggerhead Kingbird	*Tyrannus caudifasciatus.*
	Thick-billed Kingbird	*Tyrannus crassirostris.*
	Tropical Kingbird	*Tyrannus melancholicus.*
	Western Kingbird	*Tyrannus verticalis.*
Kingfisher	Amazon Kingfisher	*Chloroceryle amazona.*
	Belted Kingfisher	*Megaceryle alcyon.*
	Common Kingfisher	*Alcedo atthis.*
	Green Kingfisher	*Chloroceryle americana.*
	Guam Kingfisher	*Todiramphus cinnamominus.*
	Mariana Kingfisher	*Todiramphus albicilla.*
	Pacific Kingfisher	*Todiramphus sacer.*
	Ringed Kingfisher	*Megaceryle torquata.*
Kinglet	Golden-crowned Kinglet	*Regulus satrapa.*
	Ruby-crowned Kinglet	*Corthylio calendula.*
Kiskadee	Great Kiskadee	*Pitangus sulphuratus.*
Kite	Black Kite	*Milvus migrans.*
	Double-toothed Kite	*Harpagus bidentatus.*
	Hook-billed Kite	*Chondrohierax uncinatus.*
	Mississippi Kite	*Ictinia mississippiensis.*
	Snail Kite	*Rostrhamus sociabilis.*
	Swallow-tailed Kite	*Elanoides forficatus.*
	White-tailed Kite	*Elanus leucurus.*
Kittiwake	Black-legged Kittiwake	*Rissa tridactyla.*
	Red-legged Kittiwake	*Rissa brevirostris.*
Knot	Great Knot	*Calidris tenuirostris.*
	Red Knot	*Calidris canutus.*
Koel	Long-tailed Koel	*Urodynamis taitensis.*
Lapwing	Northern Lapwing	*Vanellus vanellus.*
Lark	Horned Lark	*Eremophila alpestris.*
Limpkin	Limpkin	*Aramus guarauna.*
Lizard-Cuckoo	Puerto Rican Lizard-Cuckoo	*Coccyzus vieilloti.*
Longspur	Chestnut-collared Longspur	*Calcarius ornatus.*
	Lapland Longspur	*Calcarius lapponicus.*
	Smith's Longspur	*Calcarius pictus.*
	Thick-billed Longspur	*Rhynchophanes mccownii.*
Loon	Arctic Loon	*Gavia arctica.*
	Common Loon	*Gavia immer.*
	Pacific Loon	*Gavia pacifica.*
	Red-throated Loon	*Gavia stellata.*
	Yellow-billed Loon	*Gavia adamsii.*
Magpie	Black-billed Magpie	*Pica hudsonia.*
	Yellow-billed Magpie	*Pica nuttalli.*
Mallard	Mallard	*Anas platyrhynchos.*
Mango	Puerto Rican Mango	*Anthracothorax aurulentus.*
	Green Mango	*Anthracothorax viridis.*
	Green-breasted Mango	*Anthracothorax prevostii.*
Marsh-Harrier	Eastern Marsh-Harrier	*Circus spilonotus.*
Martin	Brown-chested Martin	*Progne tapera.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Caribbean Martin	*Progne dominicensis.*
	Cuban Martin	*Progne cryptoleuca.*
	Gray-breasted Martin	*Progne chalybea.*
	Purple Martin	*Progne subis.*
	Southern Martin	*Progne elegans.*
Meadowlark	Chihuahuan Meadowlark	*Sturnella lilianae.*
	Eastern Meadowlark	*Sturnella magna.*
	Western Meadowlark	*Sturnella neglecta.*
Merganser	Common Merganser	*Mergus merganser.*
	Hooded Merganser	*Lophodytes cucullatus.*
	Red-breasted Merganser	*Mergus serrator.*
Merlin	Merlin	*Falco columbarius.*
Millerbird	Millerbird	*Acrocephalus familiaris.*
Mockingbird	Bahama Mockingbird	*Mimus gundlachii.*
	Blue Mockingbird	*Melanotis caerulescens.*
	Northern Mockingbird	*Mimus polyglottos.*
Moorhen	Eurasian Moorhen	*Gallinula chloropus.*
Mountain-gem	Amethyst-throated Mountain-gem	*Lampornis amethystinus.*
	Blue-throated Mountain-gem	*Lampornis clemenciae.*
Murre	Common Murre	*Uria aalge.*
	Thick-billed Murre	*Uria lomvia.*
Murrelet	Ancient Murrelet	*Synthliboramphus antiquus.*
	Craveri's Murrelet	*Synthliboramphus craveri.*
	Guadalupe Murrelet	*Synthliboramphus hypoleucus.*
	Kittlitz's Murrelet	*Brachyramphus brevirostris.*
	Long-billed Murrelet	*Brachyramphus perdix.*
	Marbled Murrelet	*Brachyramphus marmoratus.*
	Scripps's Murrelet	*Synthliboramphus scrippsi.*
Needletail	White-throated Needletail	*Hirundapus caudacutus.*
Nighthawk	Antillean Nighthawk	*Chordeiles gundlachii.*
	Common Nighthawk	*Chordeiles minor.*
	Lesser Nighthawk	*Chordeiles acutipennis.*
Night-Heron	Black-crowned Night-Heron	*Nycticorax nycticorax.*
	Japanese Night-Heron	*Gorsachius goisagi.*
	Malayan Night-Heron	*Gorsachius melanolophus.*
	Nankeen Night-Heron	*Nycticorax caledonicus.*
	Yellow-crowned Night-Heron	*Nyctanassa violacea.*
Nightingale-Thrush	Black-headed Nightingale-Thrush	*Catharus mexicanus.*
	Orange-billed Nightingale-Thrush	*Catharus aurantiirostris.*
Nightjar	Buff-collared Nightjar	*Antrostomus ridgwayi.*
	Gray Nightjar	*Caprimulgus jotaka.*
	Puerto Rican Nightjar	*Antrostomus noctitherus.*
	White-tailed Nightjar	*Hydropsalis cayennensis.*
Noddy	Black Noddy	*Anous minutus.*
	Blue-gray Noddy	*Anous ceruleus.*
	Brown Noddy	*Anous stolidus.*
Nukupu'u	Kauai Nukupu'u	*Hemignathus hanapepe.*
	Maui Nukupu'u	*Hemignathus affinis.*
	O'ahu Nukupu'u	*Hemignathus lucidus.*
Nutcracker	Clark's Nutcracker	*Nucifraga columbiana.*
Nuthatch	Brown-headed Nuthatch	*Sitta pusilla.*
	Pygmy Nuthatch	*Sitta pygmaea.*
	Red-breasted Nuthatch	*Sitta canadensis.*
	White-breasted Nuthatch	*Sitta carolinensis.*
Oloma'o	Oloma'o	*Myadestes lanaiensis.*
'Ōma'o	'Ōma'o	*Myadestes obscurus.*
Oriole	Altamira Oriole	*Icterus gularis.*
	Audubon's Oriole	*Icterus graduacauda.*
	Baltimore Oriole	*Icterus galbula.*
	Black-backed Oriole	*Icterus abeillei.*
	Black-vented Oriole	*Icterus wagleri.*
	Bullock's Oriole	*Icterus bullockii.*
	Hooded Oriole	*Icterus cucullatus.*
	Orchard Oriole	*Icterus spurius.*
	Puerto Rican Oriole	*Icterus portoricensis.*
	Scott's Oriole	*Icterus parisorum.*
	Streak-backed Oriole	*Icterus pustulatus.*
Osprey	Osprey	*Pandion haliaetus.*
'Ō'ū	'Ō'ū	*Psittirostra psittacea.*
Ovenbird	Ovenbird	*Seiurus aurocapilla.*
Owl	Barn Owl	*Tyto alba.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Barred Owl	*Strix varia.*
	Boreal Owl	*Aegolius funereus.*
	Burrowing Owl	*Athene cunicularia.*
	Elf Owl	*Micrathene whitneyi.*
	Flammulated Owl	*Psiloscops flammeolus.*
	Great Gray Owl	*Strix nebulosa.*
	Great Horned Owl	*Bubo virginianus.*
	Long-eared Owl	*Asio otus.*
	Mottled Owl	*Strix virgata.*
	Northern Hawk Owl	*Surnia ulula.*
	Northern Saw-whet Owl	*Aegolius acadicus.*
	Puerto Rican Owl	*Gymnasio nudipes.*
	Short-eared Owl	*Asio flammeus.*
	Snowy Owl	*Bubo scandiacus.*
	Spotted Owl	*Strix occidentalis.*
	Stygian Owl	*Asio stygius.*
Oystercatcher	American Oystercatcher	*Haematopus palliatus.*
	Black Oystercatcher	*Haematopus bachmani.*
	Eurasian Oystercatcher	*Haematopus ostralegus.*
Palila	Palila	*Loxioides bailleui.*
Palm-Swift	Antillean Palm-Swift	*Tachornis phoenicobia.*
Parrotbill	Maui Parrotbill	*Pseudonestor xanthophrys.*
Parula	Northern Parula	*Setophaga americana.*
	Tropical Parula	*Setophaga pitiayumi.*
Pauraque	Common Pauraque	*Nyctidromus albicollis.*
Pelican	American White Pelican	*Pelecanus erythrorhynchos.*
	Brown Pelican	*Pelecanus occidentalis.*
Petrel	Bermuda Petrel	*Pterodroma cahow.*
	Black-capped Petrel	*Pterodroma hasitata.*
	Black-winged Petrel	*Pterodroma nigripennis.*
	Bonin Petrel	*Pterodroma hypoleuca.*
	Bulwer's Petrel	*Bulweria bulwerii.*
	Cook's Petrel	*Pterodroma cookii.*
	Fea's Petrel	*Pterodroma feae.*
	Gould's Petrel	*Pterodroma leucoptera.*
	Gray-faced Petrel	*Pterodroma gouldi.*
	Hawaiian Petrel	*Pterodroma sandwichensis.*
	Herald Petrel	*Pterodroma heraldica.*
	Jouanin's Petrel	*Bulweria fallax.*
	Juan Fernandez Petrel	*Pterodroma externa.*
	Kermadec Petrel	*Pterodroma neglecta.*
	Mottled Petrel	*Pterodroma inexpectata.*
	Murphy's Petrel	*Pterodroma ultima.*
	Parkinson's Petrel	*Procellaria parkinsoni.*
	Phoenix Petrel	*Pterodroma alba.*
	Providence Petrel	*Pterodroma solandri.*
	Stejneger's Petrel	*Pterodroma longirostris.*
	Tahiti Petrel	*Pseudobulweria rostrata.*
	Trindade Petrel	*Pterodroma arminjoniana.*
	White-chinned Petrel	*Procellaria aequinoctialis.*
	White-necked Petrel	*Pterodroma cervicalis.*
	Zino's Petrel	*Pterodroma madeira.*
Pewee	Cuban Pewee	*Contopus caribaeus.*
	Greater Pewee	*Contopus pertinax.*
	Hispaniolan Pewee	*Contopus hispaniolensis.*
	Lesser Antillean Pewee	*Contopus latirostris.*
Phainopepla	Phainopepla	*Phainopepla nitens.*
Phalarope	Red Phalarope	*Phalaropus fulicarius.*
	Red-necked Phalarope	*Phalaropus lobatus.*
	Wilson's Phalarope	*Phalaropus tricolor.*
Phoebe	Black Phoebe	*Sayornis nigricans.*
	Eastern Phoebe	*Sayornis phoebe.*
	Say's Phoebe	*Sayornis saya.*
Pigeon	Band-tailed Pigeon	*Patagioenas fasciata.*
	Plain Pigeon	*Patagioenas inornata.*
	Red-billed Pigeon	*Patagioenas flavirostris.*
	Scaly-naped Pigeon	*Patagioenas squamosa.*
	White-crowned Pigeon	*Patagioenas leucocephala.*
Pintail	Northern Pintail	*Anas acuta.*
	White-cheeked Pintail	*Anas bahamensis.*
Pipit	American Pipit	*Anthus rubescens.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Olive-backed Pipit	*Anthus hodgsoni.*
	Pechora Pipit	*Anthus gustavi.*
	Red-throated Pipit	*Anthus cervinus.*
	Sprague's Pipit	*Anthus spragueii.*
	Tree Pipit	*Anthus trivialis.*
Plover	Black-bellied Plover	*Pluvialis squatarola.*
	Collared Plover	*Charadrius collaris.*
	Common Ringed Plover	*Charadrius hiaticula.*
	Kentish Plover	*Charadrius alexandrinus.*
	Little Ringed Plover	*Charadrius dubius.*
	Mountain Plover	*Charadrius montanus.*
	Piping Plover	*Charadrius melodus.*
	Semipalmated Plover	*Charadrius semipalmatus.*
	Snowy Plover	*Charadrius nivosus.*
	Wilson's Plover	*Charadrius wilsonia.*
Pochard	Baer's Pochard	*Aythya baeri.*
	Common Pochard	*Aythya ferina.*
Pond-Heron	Chinese Pond-Heron	*Ardeola bacchus.*
Poorwill	Common Poorwill	*Phalaenoptilus nuttallii.*
Po'ouli	Po'ouli	*Melamprosops phaeosoma.*
Puaiohi	Puaiohi	*Myadestes palmeri.*
Puffin	Atlantic Puffin	*Fratercula arctica.*
	Horned Puffin	*Fratercula corniculata.*
	Tufted Puffin	*Fratercula cirrhata.*
Pygmy-Owl	Ferruginous Pygmy-Owl	*Glaucidium brasilianum.*
	Northern Pygmy-Owl	*Glaucidium gnoma.*
Pyrrhuloxia	Pyrrhuloxia	*Cardinalis sinuatus.*
Quail-Dove	Bridled Quail-Dove	*Geotrygon mystacea.*
	Key West Quail-Dove	*Geotrygon chrysia.*
	Ruddy Quail-Dove	*Geotrygon montana.*
Quetzal	Eared Quetzal	*Euptilotis neoxenus.*
Rail	Black Rail	*Laterallus jamaicensis.*
	Buff-banded Rail	*Gallirallus philippensis.*
	Clapper Rail	*Rallus crepitans.*
	Guam Rail	*Gallirallus owstoni.*
	King Rail	*Rallus elegans.*
	Ridgway's Rail	*Rallus obsoletus.*
	Spotted Rail	*Pardirallus maculatus.*
	Virginia Rail	*Rallus limicola.*
	Yellow Rail	*Coturnicops noveboracensis.*
Raven	Chihuahuan Raven	*Corvus cryptoleucus.*
	Common Raven	*Corvus corax.*
Razorbill	Razorbill	*Alca torda.*
Redhead	Redhead	*Aythya americana.*
Redpoll	Common Redpoll	*Acanthis flammea.*
	Hoary Redpoll	*Acanthis hornemanni.*
Redshank	Common Redshank	*Tringa totanus.*
	Spotted Redshank	*Tringa erythropus.*
Redstart	American Redstart	*Setophaga ruticilla.*
	Common Redstart	*Phoenicurus phoenicurus.*
	Painted Redstart	*Myioborus pictus.*
	Slate-throated Redstart	*Myioborus miniatus.*
Redwing	Redwing	*Turdus iliacus.*
Reef-Heron	Pacific Reef-Heron	*Egretta sacra.*
	Western Reef-Heron	*Egretta gularis.*
Roadrunner	Greater Roadrunner	*Geococcyx californianus.*
Robin	American Robin	*Turdus migratorius.*
	European Robin	*Erithacus rubecula.*
	Rufous-backed Robin	*Turdus rufopalliatus.*
	Rufous-tailed Robin	*Larvivora sibilans.*
	Siberian Blue Robin	*Larvivora cyane.*
Rock-Thrush	Blue Rock-Thrush	*Monticola solitarius.*
Rosefinch	Common Rosefinch	*Carpodacus erythrinus.*
	Pallas's Rosefinch	*Carpodacus roseus.*
Rosy-Finch	Asian Rosy-Finch	*Leucosticte arctoa.*
	Black Rosy-Finch	*Leucosticte atrata.*
	Brown-capped Rosy-Finch	*Leucosticte australis.*
	Gray-crowned Rosy-Finch	*Leucosticte tephrocotis.*
Rubythroat	Siberian Rubythroat	*Calliope calliope.*
Ruff	Ruff	*Calidris pugnax.*
Sanderling	Sanderling	*Calidris alba.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Sandpiper	Baird's Sandpiper	*Calidris bairdii.*
	Broad-billed Sandpiper	*Calidris falcinellus.*
	Buff-breasted Sandpiper	*Calidris subruficollis.*
	Common Sandpiper	*Actitis hypoleucos.*
	Curlew Sandpiper	*Calidris ferruginea.*
	Green Sandpiper	*Tringa ochropus.*
	Least Sandpiper	*Calidris minutilla.*
	Marsh Sandpiper	*Tringa stagnatilis.*
	Pectoral Sandpiper	*Calidris melanotos.*
	Purple Sandpiper	*Calidris maritima.*
	Rock Sandpiper	*Calidris ptilocnemis.*
	Semipalmated Sandpiper	*Calidris pusilla.*
	Sharp-tailed Sandpiper	*Calidris acuminata.*
	Solitary Sandpiper	*Tringa solitaria.*
	Spoon-billed Sandpiper	*Calidris pygmea.*
	Spotted Sandpiper	*Actitis macularius.*
	Stilt Sandpiper	*Calidris himantopus.*
	Terek Sandpiper	*Xenus cinereus.*
	Upland Sandpiper	*Bartramia longicauda.*
	Western Sandpiper	*Calidris mauri.*
	White-rumped Sandpiper	*Calidris fuscicollis.*
	Wood Sandpiper	*Tringa glareola.*
Sand-Plover	Greater Sand-Plover	*Charadrius leschenaultii.*
	Lesser Sand-Plover	*Charadrius mongolus.*
Sapsucker	Red-breasted Sapsucker	*Sphyrapicus ruber.*
	Red-naped Sapsucker	*Sphyrapicus nuchalis.*
	Williamson's Sapsucker	*Sphyrapicus thyroideus.*
	Yellow-bellied Sapsucker	*Sphyrapicus varius.*
Scaup	Greater Scaup	*Aythya marila.*
	Lesser Scaup	*Aythya affinis.*
Scops-Owl	Oriental Scops-Owl	*Otus sunia.*
Scoter	Black Scoter	*Melanitta americana.*
	Common Scoter	*Melanitta nigra.*
	Stejneger's Scoter	*Melanitta stejneger.*
	Surf Scoter	*Melanitta perspicillata.*
	White-winged Scoter	*Melanitta deglandi.*
Screech-Owl	Eastern Screech-Owl	*Megascops asio.*
	Western Screech-Owl	*Megascops kennicottii.*
	Whiskered Screech-Owl	*Megascops trichopsis.*
Scrub-Jay	California Scrub-Jay	*Aphelocoma californica.*
	Florida Scrub-Jay	*Aphelocoma coerulescens.*
	Island Scrub-Jay	*Aphelocoma insularis.*
	Woodhouse's Scrub-Jay	*Aphelocoma woodhouseii.*
Sea-Eagle	Steller's Sea-Eagle	*Haliaeetus pelagicus.*
Seedeater	Morelet's Seedeater	*Sporophila morelleti.*
Shearwater	Audubon's Shearwater	*Puffinus lherminieri.*
	Barolo Shearwater	*Puffinus baroli.*
	Black-vented Shearwater	*Puffinus opisthomelas.*
	Bryan's Shearwater	*Puffinus bryani.*
	Buller's Shearwater	*Ardenna bulleri.*
	Cape Verde Shearwater	*Calonectris edwardsii.*
	Christmas Shearwater	*Puffinus nativitatis.*
	Cory's Shearwater	*Calonectris diomedea.*
	Flesh-footed Shearwater	*Ardenna carneipes.*
	Great Shearwater	*Ardenna gravis.*
	Manx Shearwater	*Puffinus puffinus.*
	Newell's Shearwater	*Puffinus newelli.*
	Pink-footed Shearwater	*Ardenna creatopus.*
	Short-tailed Shearwater	*Ardenna tenuirostris.*
	Sooty Shearwater	*Ardenna grisea.*
	Streaked Shearwater	*Calonectris leucomelas.*
	Wedge-tailed Shearwater	*Ardenna pacifica.*
Shoveler	Northern Shoveler	*Spatula clypeata.*
Shrike	Brown Shrike	*Lanius cristatus.*
	Loggerhead Shrike	*Lanius ludovicianus.*
	Northern Shrike	*Lanius borealis.*
Silky-Flycatcher	Gray Silky-Flycatcher	*Ptiliogonys cinereus.*
Siskin	Eurasian Siskin	*Spinus spinus.*
	Pine Siskin	*Spinus pinus.*
Skimmer	Black Skimmer	*Rynchops niger.*
Skua	Great Skua	*Stercorarius skua.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	South Polar Skua	*Stercorarius maccormicki.*
Skylark	Eurasian Skylark	*Alauda arvensis.*
Smew	Smew	*Mergellus albellus.*
Snipe	Common Snipe	*Gallinago gallinago.*
	Jack Snipe	*Lymnocryptes minimus.*
	Pin-tailed Snipe	*Gallinago stenura.*
	Solitary Snipe	*Gallinago solitaria.*
	Swinhoe's Snipe	*Gallinago megala.*
	Wilson's Snipe	*Gallinago delicata.*
Solitaire	Brown-backed Solitaire	*Myadestes occidentalis.*
	Townsend's Solitaire	*Myadestes townsendi.*
Sora	Sora	*Porzana carolina.*
Sparrow	American Tree Sparrow	*Spizelloides arborea.*
	Bachman's Sparrow	*Peucaea aestivalis.*
	Baird's Sparrow	*Centronyx bairdii.*
	Bell's Sparrow	*Artemisiospiza belli.*
	Black-chinned Sparrow	*Spizella atrogularis.*
	Black-throated Sparrow	*Amphispiza bilineata.*
	Botteri's Sparrow	*Peucaea botterii.*
	Brewer's Sparrow	*Spizella breweri.*
	Cassin's Sparrow	*Peucaea cassinii.*
	Chipping Sparrow	*Spizella passerina.*
	Clay-colored Sparrow	*Spizella pallida.*
	Field Sparrow	*Spizella pusilla.*
	Five-striped Sparrow	*Amphispizopsis quinquestriata.*
	Fox Sparrow	*Passerella iliaca.*
	Golden-crowned Sparrow	*Zonotrichia atricapilla.*
	Grasshopper Sparrow	*Ammodramus savannarum.*
	Harris's Sparrow	*Zonotrichia querula.*
	Henslow's Sparrow	*Centronyx henslowii.*
	Lark Sparrow	*Chondestes grammacus.*
	LeConte's Sparrow	*Ammospiza leconteii.*
	Lincoln's Sparrow	*Melospiza lincolnii.*
	Nelson's Sparrow	*Ammospiza nelsoni.*
	Olive Sparrow	*Arremonops rufivirgatus.*
	Rufous-crowned Sparrow	*Aimophila ruficeps.*
	Rufous-winged Sparrow	*Peucaea carpalis.*
	Sagebrush Sparrow	*Artemisiospiza nevadensis.*
	Saltmarsh Sparrow	*Ammospiza caudacuta.*
	Savannah Sparrow	*Passerculus sandwichensis.*
	Seaside Sparrow	*Ammospiza maritima.*
	Song Sparrow	*Melospiza melodia.*
	Swamp Sparrow	*Melospiza georgiana.*
	Vesper Sparrow	*Pooecetes gramineus.*
	White-crowned Sparrow	*Zonotrichia leucophrys.*
	White-throated Sparrow	*Zonotrichia albicollis.*
	Worthen's Sparrow	*Spizella wortheni.*
Sparrowhawk	Chinese Sparrowhawk	*Accipiter soloensis.*
	Japanese Sparrowhawk	*Accipiter gularis.*
Spindalis	Puerto Rican Spindalis	*Spindalis portoricensis.*
	Western Spindalis	*Spindalis zena.*
Spoonbill	Roseate Spoonbill	*Platalea ajaja.*
Starling	Chestnut-cheeked Starling	*Agropsar philippensis.*
	White-cheeked Starling	*Spodiopsar cineraceus.*
Starthroat	Plain-capped Starthroat	*Heliomaster constantii.*
Stilt	Black-necked Stilt	*Himantopus mexicanus.*
	Black-winged Stilt	*Himantopus himantopus.*
Stint	Little Stint	*Calidris minuta.*
	Long-toed Stint	*Calidris subminuta.*
	Red-necked Stint	*Calidris ruficollis.*
	Temminck's Stint	*Calidris temminckii.*
Stonechat	Asian Stonechat	*Saxicola maurus.*
Stork	Wood Stork	*Mycteria americana.*
Storm-Petrel	Ashy Storm-Petrel	*Hydrobates homochroa.*
	Band-rumped Storm-Petrel	*Hydrobates castro.*
	Black Storm-Petrel	*Hydrobates melania.*
	Black-bellied Storm-Petrel	*Fregetta tropica.*
	European Storm-Petrel	*Hydrobates pelagicus.*
	Fork-tailed Storm-Petrel	*Hydrobates furcatus.*
	Leach's Storm-Petrel	*Hydrobates leucorhous.*
	Least Storm-Petrel	*Hydrobates microsoma.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Matsudaira's Storm-Petrel	*Hydrobates matsudairae.*
	Polynesian Storm-Petrel	*Nesofregetta fuliginosa.*
	Ringed Storm-Petrel	*Hydrobates hornbyi.*
	Swinhoe's Storm-Petrel	*Hydrobates monorhis.*
	Townsend's Storm-Petrel	*Hydrobates socorroensis.*
	Tristram's Storm-Petrel	*Hydrobates tristrami.*
	Wedge-rumped Storm-Petrel	*Hydrobates tethys.*
	White-bellied Storm-Petrel	*Fregetta grallaria.*
	White-faced Storm-Petrel	*Pelagodroma marina.*
	Wilson's Storm-Petrel	*Oceanites oceanicus.*
Surfbird	Surfbird	*Calidris virgata.*
Swallow	Bahama Swallow	*Tachycineta cyaneoviridis.*
	Bank Swallow	*Riparia riparia.*
	Barn Swallow	*Hirundo rustica.*
	Blue-and-white Swallow	*Pygochelidon cyanoleuca.*
	Cave Swallow	*Petrochelidon fulva.*
	Cliff Swallow	*Petrochelidon pyrrhonota.*
	Mangrove Swallow	*Tachycineta albilinea.*
	Northern Rough-winged Swallow	*Stelgidopteryx serripennis.*
	Tree Swallow	*Tachycineta bicolor.*
	Violet-green Swallow	*Tachycineta thalassina.*
Swamphen	Purple Swamphen	*Porphyrio porphyrio.*
Swan	Trumpeter Swan	*Cygnus buccinator.*
	Tundra Swan	*Cygnus columbianus.*
	Whooper Swan	*Cygnus cygnus.*
Swift	Alpine Swift	*Apus melba.*
	Black Swift	*Cypseloides niger.*
	Chimney Swift	*Chaetura pelagica.*
	Common Swift	*Apus apus.*
	Fork-tailed Swift	*Apus pacificus.*
	Short-tailed Swift	*Chaetura brachyura.*
	Vaux's Swift	*Chaetura vauxi.*
	White-collared Swift	*Streptoprocne zonaris.*
	White-throated Swift	*Aeronautes saxatalis.*
Swiftlet	Mariana Swiftlet	*Aerodramus bartschi.*
	White-rumped Swiftlet	*Aerodramus spodiopygius.*
Tanager	Flame-colored Tanager	*Piranga bidentata.*
	Hepatic Tanager	*Piranga flava.*
	Puerto Rican Tanager	*Nesospingus speculiferus.*
	Scarlet Tanager	*Piranga olivacea.*
	Summer Tanager	*Piranga rubra.*
	Western Tanager	*Piranga ludoviciana.*
Tattler	Gray-tailed Tattler	*Tringa brevipes.*
	Wandering Tattler	*Tringa incana.*
Teal	Baikal Teal	*Sibirionetta formosa.*
	Blue-winged Teal	*Spatula discors.*
	Cinnamon Teal	*Spatula cyanoptera.*
	Green-winged Teal	*Anas crecca.*
Tern	Aleutian Tern	*Onychoprion aleuticus.*
	Arctic Tern	*Sterna paradisaea.*
	Black Tern	*Chlidonias niger.*
	Black-naped Tern	*Sterna sumatrana.*
	Bridled Tern	*Onychoprion anaethetus.*
	Caspian Tern	*Hydroprogne caspia.*
	Common Tern	*Sterna hirundo.*
	Elegant Tern	*Thalasseus elegans.*
	Forster's Tern	*Sterna forsteri.*
	Gray-backed Tern	*Onychoprion lunatus.*
	Great Crested Tern	*Thalasseus bergii.*
	Gull-billed Tern	*Gelochelidon nilotica.*
	Inca Tern	*Larosterna inca.*
	Large-billed Tern	*Phaetusa simplex.*
	Least Tern	*Sternula antillarum.*
	Little Tern	*Sternula albifrons.*
	Roseate Tern	*Sterna dougallii.*
	Royal Tern	*Thalasseus maximus.*
	Sandwich Tern	*Thalasseus sandvicensis.*
	Sooty Tern	*Onychoprion fuscatus.*
	Whiskered Tern	*Chlidonias hybrida.*
	White Tern	*Gygis alba.*
	White-winged Tern	*Chlidonias leucopterus.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Thrasher	Bendire's Thrasher	*Toxostoma bendirei.*
	Brown Thrasher	*Toxostoma rufum.*
	California Thrasher	*Toxostoma redivivum.*
	Crissal Thrasher	*Toxostoma crissale.*
	Curve-billed Thrasher	*Toxostoma curvirostre.*
	LeConte's Thrasher	*Toxostoma lecontei.*
	Long-billed Thrasher	*Toxostoma longirostre.*
	Pearly-eyed Thrasher	*Margarops fuscatus.*
	Sage Thrasher	*Oreoscoptes montanus.*
Thrush	Aztec Thrush	*Ridgwayia pinicola.*
	Bicknell's Thrush	*Catharus bicknelli.*
	Clay-colored Thrush	*Turdus grayi.*
	Dusky Thrush	*Turdus eunomus.*
	Eyebrowed Thrush	*Turdus obscurus.*
	Gray-cheeked Thrush	*Catharus minimus.*
	Hermit Thrush	*Catharus guttatus.*
	Naumann's Thrush	*Turdus naumanni.*
	Red-legged Thrush	*Turdus plumbeus.*
	Swainson's Thrush	*Catharus ustulatus.*
	Varied Thrush	*Ixoreus naevius.*
	White-throated Thrush	*Turdus assimilis.*
	Wood Thrush	*Hylocichla mustelina.*
Tiger-Heron	Bare-throated Tiger-Heron	*Tigrisoma mexicanum.*
Titmouse	Black-crested Titmouse	*Baeolophus atricristatus.*
	Bridled Titmouse	*Baeolophus wollweberi.*
	Juniper Titmouse	*Baeolophus ridgwayi.*
	Oak Titmouse	*Baeolophus inornatus.*
	Tufted Titmouse	*Baeolophus bicolor.*
Tityra	Masked Tityra	*Tityra semifasciata.*
Towhee	Abert's Towhee	*Melozone aberti.*
	California Towhee	*Melozone crissalis.*
	Canyon Towhee	*Melozone fusca.*
	Eastern Towhee	*Pipilo erythrophthalmus.*
	Green-tailed Towhee	*Pipilo chlorurus.*
	Spotted Towhee	*Pipilo maculatus.*
Trogon	Elegant Trogon	*Trogon elegans.*
Tropicbird	Red-billed Tropicbird	*Phaethon aethereus.*
	Red-tailed Tropicbird	*Phaethon rubricauda.*
	White-tailed Tropicbird	*Phaethon lepturus.*
Turnstone	Black Turnstone	*Arenaria melanocephala.*
	Ruddy Turnstone	*Arenaria interpres.*
Turtle-Dove	Oriental Turtle-Dove	*Streptopelia orientalis.*
Veery	Veery	*Catharus fuscescens.*
Verdin	Verdin	*Auriparus flaviceps.*
Violetear	Mexican Violetear	*Colibri thalassinus.*
Vireo	Bell's Vireo	*Vireo bellii.*
	Black-capped Vireo	*Vireo atricapilla.*
	Black-whiskered Vireo	*Vireo altiloquus.*
	Blue-headed Vireo	*Vireo solitarius.*
	Cassin's Vireo	*Vireo cassinii.*
	Cuban Vireo	*Vireo gundlachii.*
	Gray Vireo	*Vireo vicinior.*
	Hutton's Vireo	*Vireo huttoni.*
	Philadelphia Vireo	*Vireo philadelphicus.*
	Plumbeous Vireo	*Vireo plumbeus.*
	Puerto Rican Vireo	*Vireo latimeri.*
	Red-eyed Vireo	*Vireo olivaceus.*
	Thick-billed Vireo	*Vireo crassirostris.*
	Warbling Vireo	*Vireo gilvus.*
	White-eyed Vireo	*Vireo griseus.*
	Yellow-green Vireo	*Vireo flavoviridis.*
	Yellow-throated Vireo	*Vireo flavifrons.*
	Yucatan Vireo	*Vireo magister.*
Vulture	Black Vulture	*Coragyps atratus.*
	Turkey Vulture	*Cathartes aura.*
Wagtail	Citrine Wagtail	*Motacilla citreola.*
	Eastern Yellow Wagtail	*Motacilla tschutschensis.*
	Gray Wagtail	*Motacilla cinerea.*
	White Wagtail	*Motacilla alba.*
Warbler	Adelaide's Warbler	*Setophaga adelaidae.*
	Aguiguan Reed Warbler	*Acrocephalus nijoi.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
	Arctic Warbler	*Phylloscopus borealis.*
	Bachman's Warbler	*Vermivora bachmanii.*
	Bay-breasted Warbler	*Setophaga castanea.*
	Black-and-white Warbler	*Mniotilta varia.*
	Blackburnian Warbler	*Setophaga fusca.*
	Blackpoll Warbler	*Setophaga striata.*
	Black-throated Blue Warbler	*Setophaga caerulescens.*
	Black-throated Gray Warbler	*Setophaga nigrescens.*
	Black-throated Green Warbler	*Setophaga virens.*
	Blue-winged Warbler	*Vermivora cyanoptera.*
	Blyth's Reed Warbler	*Acrocephalus dumetorum.*
	Canada Warbler	*Cardellina canadensis.*
	Cape May Warbler	*Setophaga tigrina.*
	Cerulean Warbler	*Setophaga cerulea.*
	Chestnut-sided Warbler	*Setophaga pensylvanica.*
	Colima Warbler	*Leiothlypis crissalis.*
	Connecticut Warbler	*Oporornis agilis.*
	Crescent-chested Warbler	*Oreothlypis superciliosa.*
	Dusky Warbler	*Phylloscopus fuscatus.*
	Elfin-woods Warbler	*Setophaga angelae.*
	Fan-tailed Warbler	*Basileuterus lachrymosus.*
	Golden-cheeked Warbler	*Setophaga chrysoparia.*
	Golden-crowned Warbler	*Basileuterus culicivorus.*
	Golden-winged Warbler	*Vermivora chrysoptera.*
	Grace's Warbler	*Setophaga graciae.*
	Hermit Warbler	*Setophaga occidentalis.*
	Hooded Warbler	*Setophaga citrina.*
	Kamchatka Leaf Warbler	*Phylloscopus examinandus.*
	Kentucky Warbler	*Geothlypis formosa.*
	Kirtland's Warbler	*Setophaga kirtlandii.*
	Lanceolated Warbler	*Locustella lanceolata.*
	Lucy's Warbler	*Leiothlypis luciae.*
	MacGillivray's Warbler	*Geothlypis tolmiei.*
	Magnolia Warbler	*Setophaga magnolia.*
	Middendorff's Grasshopper Warbler	*Helopsaltes ochotensis.*
	Mourning Warbler	*Geothlypis philadelphia.*
	Nashville Warbler	*Leiothlypis ruficapilla.*
	Nightingale Reed Warbler	*Acrocephalus luscinius.*
	Olive Warbler	*Peucedramus taeniatus.*
	Orange-crowned Warbler	*Leiothlypis celata.*
	Pagan Reed Warbler	*Acrocephalus yamashinae.*
	Pallas's Grasshopper Warbler	*Helopsaltes certhiola.*
	Pallas's Leaf Warbler	*Phylloscopus proregulus.*
	Palm Warbler	*Setophaga palmarum.*
	Pine Warbler	*Setophaga pinus.*
	Prairie Warbler	*Setophaga discolor.*
	Prothonotary Warbler	*Protonotaria citrea.*
	Red-faced Warbler	*Cardellina rubrifrons.*
	River Warbler	*Locustella fluviatilis.*
	Rufous-capped Warbler	*Basileuterus rufifrons.*
	Saipan Reed Warbler	*Acrocephalus hiwae.*
	Sedge Warbler	*Acrocephalus schoenobaenus.*
	Swainson's Warbler	*Limnothlypis swainsonii.*
	Tennessee Warbler	*Leiothlypis peregrina.*
	Thick-billed Warbler	*Arundinax aedon.*
	Townsend's Warbler	*Setophaga townsendi.*
	Virginia's Warbler	*Leiothlypis virginiae.*
	Willow Warbler	*Phylloscopus trochilus.*
	Wilson's Warbler	*Cardellina pusilla.*
	Wood Warbler	*Phylloscopus sibilatrix.*
	Worm-eating Warbler	*Helmitheros vermivorum.*
	Yellow Warbler	*Setophaga petechia.*
	Yellow-browed Warbler	*Phylloscopus inornatus.*
	Yellow-rumped Warbler	*Setophaga coronata.*
	Yellow-throated Warbler	*Setophaga dominica.*
Waterthrush	Louisiana Waterthrush	*Parkesia motacilla.*
	Northern Waterthrush	*Parkesia noveboracensis.*
Waxwing	Bohemian Waxwing	*Bombycilla garrulus.*
	Cedar Waxwing	*Bombycilla cedrorum.*
Wheatear	Northern Wheatear	*Oenanthe oenanthe.*
	Pied Wheatear	*Oenanthe pleschanka.*

TABLE 1 TO PARAGRAPH (c)(1)—ALPHABETICAL LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Common name group	Species common name	Species scientific name
Whimbrel	Whimbrel	*Numenius phaeopus.*
Whip-poor-will	Eastern Whip-poor-will	*Antrostomus vociferus.*
	Mexican Whip-poor-will	*Antrostomus arizonae.*
Whistling-Duck	Black-bellied Whistling-Duck	*Dendrocygna autumnalis.*
	Fulvous Whistling-Duck	*Dendrocygna bicolor.*
	West Indian Whistling-Duck	*Dendrocygna arborea.*
Whitethroat	Lesser Whitethroat	*Sylvia curruca.*
Wigeon	American Wigeon	*Mareca americana.*
	Eurasian Wigeon	*Mareca penelope.*
Willet	Willet	*Tringa semipalmata.*
Woodcock	American Woodcock	*Scolopax minor.*
	Eurasian Woodcock	*Scolopax rusticola.*
Woodpecker	Acorn Woodpecker	*Melanerpes formicivorus.*
	American Three-toed Woodpecker	*Picoides dorsalis.*
	Arizona Woodpecker	*Dryobates arizonae.*
	Black-backed Woodpecker	*Picoides arcticus.*
	Downy Woodpecker	*Dryobates pubescens.*
	Gila Woodpecker	*Melanerpes uropygialis.*
	Golden-fronted Woodpecker	*Melanerpes aurifrons.*
	Great Spotted Woodpecker	*Dendrocopos major.*
	Hairy Woodpecker	*Dryobates villosus.*
	Ivory-billed Woodpecker	*Campephilus principalis.*
	Ladder-backed Woodpecker	*Dryobates scalaris.*
	Lewis's Woodpecker	*Melanerpes lewis.*
	Nuttall's Woodpecker	*Dryobates nuttallii.*
	Pileated Woodpecker	*Dryocopus pileatus.*
	Puerto Rican Woodpecker	*Melanerpes portoricensis.*
	Red-bellied Woodpecker	*Melanerpes carolinus.*
	Red-cockaded Woodpecker	*Dryobates borealis.*
	Red-headed Woodpecker	*Melanerpes erythrocephalus.*
	White-headed Woodpecker	*Dryobates albolarvatus.*
Wood-Pewee	Eastern Wood-Pewee	*Contopus virens.*
	Western Wood-Pewee	*Contopus sordidulus.*
Wood-Rail	Rufous-necked Wood-Rail	*Aramides axillaris.*
Woodstar	Bahama Woodstar	*Nesophlox evelynae.*
Wren	Bewick's Wren	*Thryomanes bewickii.*
	Cactus Wren	*Campylorhynchus brunneicapillus.*
	Canyon Wren	*Catherpes mexicanus.*
	Carolina Wren	*Thryothorus ludovicianus.*
	House Wren	*Troglodytes aedon.*
	Marsh Wren	*Cistothorus palustris.*
	Pacific Wren	*Troglodytes pacificus.*
	Rock Wren	*Salpinctes obsoletus.*
	Sedge Wren	*Cistothorus stellaris.*
	Sinaloa Wren	*Thryophilus sinaloa.*
	Winter Wren	*Troglodytes hiemalis.*
Wrentit	Wrentit	*Chamaea fasciata.*
Wryneck	Eurasian Wryneck	*Jynx torquilla.*
Yellowlegs	Greater Yellowlegs	*Tringa melanoleuca.*
	Lesser Yellowlegs	*Tringa flavipes.*
Yellowthroat	Common Yellowthroat	*Geothlypis trichas.*
	Gray-crowned Yellowthroat	*Geothlypis poliocephala.*

(2) *Taxonomic listing.* The table lists species in phylogenetic sequence by scientific name, with the common (English) name following the scientific name. To help clarify species relationships, we also provide the higher-level taxonomic categories of Order, Family, and Subfamily.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT

Species scientific name	Species common name
(i) Order Anseriformes	
Family Anatidae	
(1) Subfamily Dendrocygninae	
Dendrocygna autumnalis	Black-bellied Whistling-Duck.
Dendrocygna arborea	West Indian Whistling-Duck.
Dendrocygna bicolor	Fulvous Whistling-Duck.
(2) Subfamily Anserinae	
Anser canagicus	Emperor Goose.
Anser caerulescens	Snow Goose.
Anser rossii	Ross's Goose.
Anser albifrons	Greater White-fronted Goose.
Anser erythropus	Lesser White-fronted Goose.
Anser fabalis	Taiga Bean-Goose.
Anser serrirostris	Tundra Bean-Goose.
Anser brachyrhynchus	Pink-footed Goose.
Branta bernicla	Brant.
Branta leucopsis	Barnacle Goose.
Branta hutchinsii	Cackling Goose.
Branta canadensis	Canada Goose.
Branta sandvicensis	Hawaiian Goose.
Cygnus buccinator	Trumpeter Swan.
Cygnus columbianus	Tundra Swan.
Cygnus cygnus	Whooper Swan.
(3) Subfamily Anatinae	
Cairina moschata	Muscovy Duck.
Aix sponsa	Wood Duck.
Sibirionetta formosa	Baikal Teal.
Spatula querquedula	Garganey.
Spatula discors	Blue-winged Teal.
Spatula cyanoptera	Cinnamon Teal.
Spatula clypeata	Northern Shoveler.
Mareca strepera	Gadwall.
Mareca falcata	Falcated Duck.
Mareca penelope	Eurasian Wigeon.
Mareca americana	American Wigeon.
Anas laysanensis	Laysan Duck
Anas wyvilliana	Hawaiian Duck.
Anas zonorhyncha	Eastern Spot-billed Duck.
Anas platyrhynchos	Mallard.
Anas diazi	Mexican Duck.
Anas rubripes	American Black Duck.
Anas fulvigula	Mottled Duck.
Anas superciliosa	Pacific Black Duck.
Anas bahamensis	White-cheeked Pintail.
Anas acuta	Northern Pintail.
Anas crecca	Green-winged Teal.
Aythya valisineria	Canvasback.
Aythya americana	Redhead.
Aythya ferina	Common Pochard.
Aythya baeri	Baer's Pochard.
Aythya collaris	Ring-necked Duck.
Aythya fuligula	Tufted Duck.
Aythya marila	Greater Scaup.
Aythya affinis	Lesser Scaup.
Polysticta stelleri	Steller's Eider.
Somateria fischeri	Spectacled Eider.
Somateria spectabilis	King Eider.
Somateria mollissima	Common Eider.
Histrionicus histrionicus	Harlequin Duck.
Melanitta perspicillata	Surf Scoter.
Melanitta deglandi	White-winged Scoter.
Melanitta stejneger	Stejneger's Scoter.
Melanitta nigra	Common Scoter.
Melanitta americana	Black Scoter.
Clangula hyemalis	Long-tailed Duck.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Bucephala albeola	Bufflehead.
Bucephala clangula	Common Goldeneye.
Bucephala islandica	Barrow's Goldeneye.
Mergellus albellus	Smew.
Lophodytes cucullatus	Hooded Merganser.
Mergus merganser	Common Merganser.
Mergus serrator	Red-breasted Merganser.
Nomonyx dominicus	Masked Duck.
Oxyura jamaicensis	Ruddy Duck.
(ii) Order Phoenicopteriformes	
Family Phoenicopteridae	
Phoenicopterus ruber	American Flamingo.
(iii) Order Podicipediformes	
Family Podicipedidae	
Tachybaptus dominicus	Least Grebe.
Podilymbus podiceps	Pied-billed Grebe.
Podiceps auritus	Horned Grebe.
Podiceps grisegena	Red-necked Grebe.
Podiceps nigricollis	Eared Grebe.
Aechmophorus occidentalis	Western Grebe.
Aechmophorus clarkii	Clark's Grebe.
(iv) Order Columbiformes	
Family Columbidae	
Patagioenas squamosa	Scaly-naped Pigeon.
Patagioenas leucocephala	White-crowned Pigeon.
Patagioenas flavirostris	Red-billed Pigeon.
Patagioenas inornata	Plain Pigeon.
Patagioenas fasciata	Band-tailed Pigeon.
Streptopelia orientalis	Oriental Turtle-Dove.
Alopecoenas stairi	Shy Ground Dove.
Alopecoenas xanthonurus	White-throated Ground Dove.
Columbina inca	Inca Dove.
Columbina passerina	Common Ground Dove.
Columbina talpacoti	Ruddy Ground Dove.
Geotrygon montana	Ruddy Quail-Dove.
Geotrygon chrysia	Key West Quail-Dove.
Geotrygon mystacea	Bridled Quail-Dove.
Leptotila verreauxi	White-tipped Dove.
Zenaida asiatica	White-winged Dove.
Zenaida aurita	Zenaida Dove.
Zenaida macroura	Mourning Dove.
Ptilinopus perousii	Many-colored Fruit-Dove.
Ptilinopus porphyraceus	Crimson-crowned Fruit-Dove.
Ptilinopus roseicapilla	Mariana Fruit-Dove.
Ducula pacifica	Pacific Imperial-Pigeon.
(v) Order Cuculiformes	
Family Cuculidae	
(1) Subfamily Crotophaginae	
Crotophaga ani	Smooth-billed Ani.
Crotophaga sulcirostris	Groove-billed Ani.
(2) Subfamily Neomorphinae	
Geococcyx californianus	Greater Roadrunner.
(3) Subfamily Cuculinae	
Urodynamis taitensis	Long-tailed Koel.
Hierococcyx nisicolor	Hodgson's Hawk-Cuckoo.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Cuculus canorus	Common Cuckoo.
Cuculus optatus	Oriental Cuckoo.
Clamator coromandus	Chestnut-winged Cuckoo.
Coccyzus melacoryphus	Dark-billed Cuckoo.
Coccyzus americanus	Yellow-billed Cuckoo.
Coccyzus minor	Mangrove Cuckoo.
Coccyzus erythropthalmus	Black-billed Cuckoo.
Coccyzus vieilloti	Puerto Rican Lizard-Cuckoo.
(vi) Order Caprimulgiformes	
Family Caprimulgidae	
(1) Subfamily Chordeilinae	
Chordeiles acutipennis	Lesser Nighthawk.
Chordeiles minor	Common Nighthawk.
Chordeiles gundlachii	Antillean Nighthawk.
(2) Subfamily Caprimulginae	
Nyctidromus albicollis	Common Pauraque.
Phalaenoptilus nuttallii	Common Poorwill.
Antrostomus carolinensis	Chuck-will's-widow.
Antrostomus ridgwayi	Buff-collared Nightjar.
Antrostomus vociferus	Eastern Whip-poor-will.
Antrostomus arizonae	Mexican Whip-poor-will.
Antrostomus noctitherus	Puerto Rican Nightjar.
Hydropsalis cayennensis	White-tailed Nightjar.
Caprimulgus jotaka	Gray Nightjar.
(vii) Order Apodiformes	
(A) Family Apodidae	
(1) Subfamily Cypseloidinae	
Cypseloides niger	Black Swift.
Streptoprocne zonaris	White-collared Swift.
(2) Subfamily Chaeturinae	
Chaetura pelagica	Chimney Swift.
Chaetura vauxi	Vaux's Swift.
Chaetura brachyura	Short-tailed Swift.
Hirundapus caudacutus	White-throated Needletail.
Aerodramus spodiopygius	White-rumped Swiftlet.
Aerodramus bartschi	Mariana Swiftlet.
(3) Subfamily Apodinae	
Apus apus	Common Swift.
Apus pacificus	Fork-tailed Swift.
Apus melba	Alpine Swift.
Aeronautes saxatalis	White-throated Swift.
Tachornis phoenicobia	Antillean Palm-Swift.
(B) Family Trochilidae	
Subfamily Trochilinae	
Colibri thalassinus	Mexican Violetear.
Anthracothorax prevostii	Green-breasted Mango.
Anthracothorax aurulentus	Puerto Rican Mango.
Anthracothorax viridis	Green Mango.
Eulampis jugularis	Purple-throated Carib.
Eulampis holosericeus	Green-throated Carib.
Eugenes fulgens	Rivoli's Hummingbird.
Heliomaster constantii	Plain-capped Starthroat.
Lampornis amethystinus	Amethyst-throated Mountain-gem.
Lampornis clemenciae	Blue-throated Mountain-gem.
Calothorax lucifer	Lucifer Hummingbird.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Archilochus colubris	Ruby-throated Hummingbird.
Archilochus alexandri	Black-chinned Hummingbird.
Mellisuga minima	Vervain Hummingbird.
Nesophlox evelynae	Bahama Woodstar.
Calypte anna	Anna's Hummingbird.
Calypte costae	Costa's Hummingbird.
Selasphorus calliope	Calliope Hummingbird.
Selasphorus rufus	Rufous Hummingbird.
Selasphorus sasin	Allen's Hummingbird.
Selasphorus platycercus	Broad-tailed Hummingbird.
Selasphorus heloisa	Bumblebee Hummingbird.
Riccordia maugaeus	Puerto Rican Emerald.
Cynanthus latirostris	Broad-billed Hummingbird.
Basilinna leucotis	White-eared Hummingbird.
Basilinna xantusii	Xantus's Hummingbird.
Orthorhyncus cristatus	Antillean Crested Hummingbird.
Ramosomyia violiceps	Violet-crowned Hummingbird.
Saucerottia beryllina	Berylline Hummingbird.
Amazilia rutila	Cinnamon Hummingbird.
Amazilia yucatanensis	Buff-bellied Hummingbird.
(viii) Order Gruiformes	
(A) Family Rallidae	
Gallirallus philippensis	Buff-banded Rail.
Gallirallus owstoni	Guam Rail.
Neocrex erythrops	Paint-billed Crake.
Pardirallus maculatus	Spotted Rail.
Aramides axillaris	Rufous-necked Wood-Rail.
Rallus obsoletus	Ridgway's Rail.
Rallus elegans	King Rail.
Rallus crepitans	Clapper Rail.
Rallus limicola	Virginia Rail.
Crex crex	Corn Crake.
Porzana carolina	Sora.
Gallinula galeata	Common Gallinule.
Gallinula chloropus	Eurasian Moorhen.
Fulica atra	Eurasian Coot.
Fulica alai	Hawaiian Coot.
Fulica americana	American Coot.
Porphyrio martinicus	Purple Gallinule.
Porphyrio flavirostris	Azure Gallinule.
Porphyrio porphyrio	Purple Swamphen.
Porzana tabuensis	Spotless Crake.
Coturnicops noveboracensis	Yellow Rail.
Hapalocrex flaviventer	Yellow-breasted Crake.
Laterallus jamaicensis	Black Rail.
(B) Family Aramidae	
Aramus guarauna	Limpkin.
(C) Family Gruidae	
Subfamily Gruinae	
Antigone canadensis	Sandhill Crane.
Grus grus	Common Crane.
Grus monacha	Hooded Crane.
Grus americana	Whooping Crane.
(ix) Order Charadriiformes	
(A) Family Recurvirostridae	
Himantopus himantopus	Black-winged Stilt.
Himantopus mexicanus	Black-necked Stilt.
Recurvirostra americana	American Avocet.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
(B) Family Haematopodidae	
Haematopus ostralegus	Eurasian Oystercatcher.
Haematopus palliatus	American Oystercatcher.
Haematopus bachmani	Black Oystercatcher.
(C) Family Charadriidae	
(1) Subfamily Vanellinae	
Vanellus vanellus	Northern Lapwing.
(2) Subfamily Charadriinae	
Pluvialis squatarola	Black-bellied Plover.
Pluvialis apricaria	European Golden-Plover.
Pluvialis dominica	American Golden-Plover.
Pluvialis fulva	Pacific Golden-Plover.
Charadrius morinellus	Eurasian Dotterel.
Charadrius vociferus	Killdeer.
Charadrius hiaticula	Common Ringed Plover.
Charadrius semipalmatus	Semipalmated Plover.
Charadrius melodus	Piping Plover.
Charadrius dubius	Little Ringed Plover.
Charadrius mongolus	Lesser Sand-Plover.
Charadrius leschenaultii	Greater Sand-Plover.
Charadrius wilsonia	Wilson's Plover.
Charadrius collaris	Collared Plover.
Charadrius alexandrinus	Kentish Plover.
Charadrius montanus	Mountain Plover.
Charadrius nivosus	Snowy Plover.
(D) Family Jacanidae	
Jacana spinosa	Northern Jacana.
(E) Family Scolopacidae	
(1) Subfamily Numeniinae	
Bartramia longicauda	Upland Sandpiper.
Numenius tahitiensis	Bristle-thighed Curlew.
Numenius phaeopus	Whimbrel.
Numenius minutus	Little Curlew.
Numenius borealis	Eskimo Curlew.
Numenius americanus	Long-billed Curlew.
Numenius madagascariensis	Far Eastern Curlew.
Numenius arquata	Eurasian Curlew.
(2) Subfamily Limosinae	
Limosa lapponica	Bar-tailed Godwit.
Limosa limosa	Black-tailed Godwit.
Limosa haemastica	Hudsonian Godwit.
Limosa fedoa	Marbled Godwit.
(3) Subfamily Arenariinae	
Arenaria interpres	Ruddy Turnstone.
Arenaria melanocephala	Black Turnstone.
Calidris tenuirostris	Great Knot.
Calidris canutus	Red Knot.
Calidris virgata	Surfbird.
Calidris pugnax	Ruff.
Calidris falcinellus	Broad-billed Sandpiper.
Calidris acuminata	Sharp-tailed Sandpiper.
Calidris himantopus	Stilt Sandpiper.
Calidris ferruginea	Curlew Sandpiper.
Calidris temminckii	Temminck's Stint.
Calidris subminuta	Long-toed Stint.
Calidris pygmea	Spoon-billed Sandpiper.
Calidris ruficollis	Red-necked Stint.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Calidris alba	Sanderling.
Calidris alpina	Dunlin.
Calidris ptilocnemis	Rock Sandpiper.
Calidris maritima	Purple Sandpiper.
Calidris bairdii	Baird's Sandpiper.
Calidris minuta	Little Stint.
Calidris minutilla	Least Sandpiper.
Calidris fuscicollis	White-rumped Sandpiper.
Calidris subruficollis	Buff-breasted Sandpiper.
Calidris melanotos	Pectoral Sandpiper.
Calidris pusilla	Semipalmated Sandpiper.
Calidris mauri	Western Sandpiper.
(4) Subfamily Scolopacinae	
Limnodromus griseus	Short-billed Dowitcher.
Limnodromus scolopaceus	Long-billed Dowitcher.
Lymnocryptes minimus	Jack Snipe.
Scolopax rusticola	Eurasian Woodcock.
Scolopax minor	American Woodcock.
Gallinago solitaria	Solitary Snipe.
Gallinago stenura	Pin-tailed Snipe.
Gallinago megala	Swinhoe's Snipe.
Gallinago gallinago	Common Snipe.
Gallinago delicata	Wilson's Snipe.
(5) Subfamily Tringinae	
Xenus cinereus	Terek Sandpiper.
Actitis hypoleucos	Common Sandpiper.
Actitis macularius	Spotted Sandpiper.
Tringa ochropus	Green Sandpiper.
Tringa solitaria	Solitary Sandpiper.
Tringa brevipes	Gray-tailed Tattler.
Tringa incana	Wandering Tattler.
Tringa flavipes	Lesser Yellowlegs.
Tringa semipalmata	Willet.
Tringa erythropus	Spotted Redshank.
Tringa nebularia	Common Greenshank.
Tringa guttifer	Nordmann's Greenshank.
Tringa melanoleuca	Greater Yellowlegs.
Tringa totanus	Common Redshank.
Tringa glareola	Wood Sandpiper.
Tringa stagnatilis	Marsh Sandpiper.
Phalaropus tricolor	Wilson's Phalarope.
Phalaropus lobatus	Red-necked Phalarope.
Phalaropus fulicarius	Red Phalarope.
(F) Family Stercorariidae	
Stercorarius skua	Great Skua.
Stercorarius maccormicki	South Polar Skua.
Stercorarius pomarinus	Pomarine Jaeger.
Stercorarius parasiticus	Parasitic Jaeger.
Stercorarius longicaudus	Long-tailed Jaeger.
(G) Family Alcidae	
Alle alle	Dovekie.
Uria aalge	Common Murre.
Uria lomvia	Thick-billed Murre.
Alca torda	Razorbill.
Cepphus grylle	Black Guillemot.
Cepphus columba	Pigeon Guillemot.
Brachyramphus perdix	Long-billed Murrelet.
Brachyramphus marmoratus	Marbled Murrelet
Brachyramphus brevirostris	Kittlitz's Murrelet.
Synthliboramphus scrippsi	Scripps's Murrelet.
Synthliboramphus hypoleucus	Guadalupe Murrelet.
Synthliboramphus craveri	Craveri's Murrelet.
Synthliboramphus antiquus	Ancient Murrelet.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Ptychoramphus aleuticus	Cassin's Auklet.
Aethia psittacula	Parakeet Auklet.
Aethia pusilla	Least Auklet.
Aethia pygmaea	Whiskered Auklet.
Aethia cristatella	Crested Auklet.
Cerorhinca monocerata	Rhinoceros Auklet.
Fratercula arctica	Atlantic Puffin.
Fratercula corniculata	Horned Puffin.
Fratercula cirrhata	Tufted Puffin.
(H) Family Laridae	
(1) Subfamily Larinae	
Creagrus furcatus	Swallow-tailed Gull.
Rissa tridactyla	Black-legged Kittiwake.
Rissa brevirostris	Red-legged Kittiwake.
Pagophila eburnea	Ivory Gull.
Xema sabini	Sabine's Gull.
Chroicocephalus philadelphia	Bonaparte's Gull.
Chroicocephalus cirrocephalus	Gray-hooded Gull.
Chroicocephalus ridibundus	Black-headed Gull.
Hydrocoloeus minutus	Little Gull.
Rhodostethia rosea	Ross's Gull.
Leucophaeus atricilla	Laughing Gull.
Leucophaeus pipixcan	Franklin's Gull.
Ichthyaetus ichthyaetus	Pallas's Gull.
Larus belcheri	Belcher's Gull.
Larus crassirostris	Black-tailed Gull.
Larus heermanni	Heermann's Gull.
Larus canus	Common Gull.
Larus brachyrhynchus	Short-billed Gull.
Larus delawarensis	Ring-billed Gull.
Larus occidentalis	Western Gull.
Larus livens	Yellow-footed Gull.
Larus californicus	California Gull.
Larus argentatus	Herring Gull.
Larus michahellis	Yellow-legged Gull.
Larus glaucoides	Iceland Gull.
Larus fuscus	Lesser Black-backed Gull.
Larus schistisagus	Slaty-backed Gull.
Larus glaucescens	Glaucous-winged Gull.
Larus hyperboreus	Glaucous Gull.
Larus marinus	Great Black-backed Gull.
Larus dominicanus	Kelp Gull.
(2) Subfamily Sterninae	
Anous stolidus	Brown Noddy.
Anous minutus	Black Noddy.
Anous ceruleus	Blue-gray Noddy.
Gygis alba	White Tern.
Onychoprion fuscatus	Sooty Tern.
Onychoprion lunatus	Gray-backed Tern.
Onychoprion anaethetus	Bridled Tern.
Onychoprion aleuticus	Aleutian Tern.
Sternula albifrons	Little Tern.
Sternula antillarum	Least Tern.
Phaetusa simplex	Large-billed Tern.
Gelochelidon nilotica	Gull-billed Tern.
Hydroprogne caspia	Caspian Tern.
Larosterna inca	Inca Tern.
Chlidonias niger	Black Tern.
Chlidonias leucopterus	White-winged Tern.
Chlidonias hybrida	Whiskered Tern.
Sterna dougallii	Roseate Tern.
Sterna sumatrana	Black-naped Tern.
Sterna hirundo	Common Tern.
Sterna paradisaea	Arctic Tern.
Sterna forsteri	Forster's Tern.
Thalasseus maximus	Royal Tern.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Thalasseus bergii	Great Crested Tern.
Thalasseus sandvicensis	Sandwich Tern.
Thalasseus elegans	Elegant Tern.
(3) Subfamily Rynchopinae	
Rynchops niger	Black Skimmer.
(x) Order Phaethontiformes	
Family Phaethontidae	
Phaethon lepturus	White-tailed Tropicbird.
Phaethon aethereus	Red-billed Tropicbird.
Phaethon rubricauda	Red-tailed Tropicbird.
(xi) Order Gaviiformes	
Family Gaviidae	
Gavia stellata	Red-throated Loon.
Gavia arctica	Arctic Loon.
Gavia pacifica	Pacific Loon.
Gavia immer	Common Loon.
Gavia adamsii	Yellow-billed Loon.
(xii) Order Procellariiformes	
(A) Family Diomedeidae	
Thalassarche chlororhynchos	Yellow-nosed Albatross.
Thalassarche cauta	White-capped Albatross.
Thalassarche eremita	Chatham Albatross.
Thalassarche salvini	Salvin's Albatross.
Thalassarche melanophris	Black-browed Albatross.
Phoebetria palpebrata	Light-mantled Albatross.
Diomedea exulans	Wandering Albatross.
Phoebastria immutabilis	Laysan Albatross.
Phoebastria nigripes	Black-footed Albatross.
Phoebastria albatrus	Short-tailed Albatross.
(B) Family Oceanitidae	
Family Phaethontidae	
Oceanites oceanicus	Wilson's Storm-Petrel.
Pelagodroma marina	White-faced Storm-Petrel.
Fregetta grallaria	White-bellied Storm-Petrel.
Fregetta tropica	Black-bellied Storm-Petrel.
Nesofregetta fuliginosa	Polynesian Storm-Petrel.
(C) Family Hydrobatidae	
Hydrobates pelagicus	European Storm-Petrel.
Hydrobates furcatus	Fork-tailed Storm-Petrel.
Hydrobates hornbyi	Ringed Storm-Petrel.
Hydrobates monorhis	Swinhoe's Storm-Petrel.
Hydrobates leucorhous	Leach's Storm-Petrel.
Hydrobates socorroensis	Townsend's Storm-Petrel.
Hydrobates homochroa	Ashy Storm-Petrel.
Hydrobates castro	Band-rumped Storm-Petrel.
Hydrobates tethys	Wedge-rumped Storm-Petrel.
Hydrobates melania	Black Storm-Petrel.
Hydrobates matsudairae	Matsudaira's Storm-Petrel.
Hydrobates tristrami	Tristram's Storm-Petrel.
Hydrobates microsoma	Least Storm-Petrel.
(D) Family Procellariidae	
Macronectes halli	Northern Giant-Petrel.
Fulmarus glacialis	Northern Fulmar.
Pterodroma gouldi	Gray-faced Petrel.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Pterodroma solandri	Providence Petrel.
Pterodroma neglecta	Kermadec Petrel.
Pterodroma arminjoniana	Trindade Petrel.
Pterodroma heraldica	Herald Petrel.
Pterodroma ultima	Murphy's Petrel.
Pterodroma inexpectata	Mottled Petrel.
Pterodroma cahow	Bermuda Petrel.
Pterodroma hasitata	Black-capped Petrel.
Pterodroma externa	Juan Fernandez Petrel.
Pterodroma sandwichensis	Hawaiian Petrel.
Pterodroma cervicalis	White-necked Petrel.
Pterodroma hypoleuca	Bonin Petrel.
Pterodroma nigripennis	Black-winged Petrel.
Pterodroma feae	Fea's Petrel.
Pterodroma madeira	Zino's Petrel.
Pterodroma cookii	Cook's Petrel.
Pterodroma leucoptera	Gould's Petrel.
Pterodroma longirostris	Stejneger's Petrel.
Pterodroma alba	Phoenix Petrel.
Pseudobulweria rostrata	Tahiti Petrel.
Bulweria bulwerii	Bulwer's Petrel.
Bulweria fallax	Jouanin's Petrel.
Procellaria aequinoctialis	White-chinned Petrel.
Procellaria parkinsoni	Parkinson's Petrel.
Calonectris leucomelas	Streaked Shearwater.
Calonectris diomedea	Cory's Shearwater.
Calonectris edwardsii	Cape Verde Shearwater.
Ardenna pacifica	Wedge-tailed Shearwater.
Ardenna bulleri	Buller's Shearwater.
Ardenna tenuirostris	Short-tailed Shearwater.
Ardenna grisea	Sooty Shearwater.
Ardenna gravis	Great Shearwater.
Ardenna creatopus	Pink-footed Shearwater.
Ardenna carneipes	Flesh-footed Shearwater.
Puffinus nativitatis	Christmas Shearwater.
Puffinus puffinus	Manx Shearwater.
Puffinus newelli	Newell's Shearwater.
Puffinus bryani	Bryan's Shearwater.
Puffinus opisthomelas	Black-vented Shearwater.
Puffinus lherminieri	Audubon's Shearwater.
Puffinus baroli	Barolo Shearwater.
(xiii) Order Ciconiiformes	
Family Ciconiidae	
Jabiru mycteria	Jabiru.
Mycteria americana	Wood Stork.
(xiv) Order Suliformes	
(A) Family Fregatidae	
Fregata ariel	Lesser Frigatebird.
Fregata magnificens	Magnificent Frigatebird.
Fregata minor	Great Frigatebird.
(B) Family Sulidae	
Sula dactylatra	Masked Booby.
Sula granti	Nazca Booby.
Sula nebouxii	Blue-footed Booby.
Sula leucogaster	Brown Booby.
Sula sula	Red-footed Booby.
Papasula abbotti	Abbott's Booby.
Morus bassanus	Northern Gannet.
(C) Family Anhingidae	
Anhinga anhinga	Anhinga.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
(D) Family Phalacrocoracidae	
Microcarbo melanoleucos	Little Pied Cormorant.
Urile penicillatus	Brandt's Cormorant.
Urile urile	Red-faced Cormorant.
Urile pelagicus	Pelagic Cormorant.
Phalacrocorax carbo	Great Cormorant.
Nannopterum auritum	Double-crested Cormorant.
Nannopterum brasilianum	Neotropic Cormorant.
(xv) Order Pelecaniformes	
(A) Family Pelecanidae	
Pelecanus erythrorhynchos	American White Pelican.
Pelecanus occidentalis	Brown Pelican.
(B) Family Ardeidae	
Botaurus lentiginosus	American Bittern.
Ixobrychus sinensis	Yellow Bittern.
Ixobrychus exilis	Least Bittern.
Ixobrychus eurhythmus	Schrenck's Bittern.
Ixobrychus flavicollis	Black Bittern.
Tigrisoma mexicanum	Bare-throated Tiger-Heron.
Ardea herodias	Great Blue Heron.
Ardea cinerea	Gray Heron.
Ardea alba	Great Egret.
Ardea intermedia	Intermediate Egret.
Egretta eulophotes	Chinese Egret.
Egretta garzetta	Little Egret.
Egretta sacra	Pacific Reef-Heron.
Egretta gularis	Western Reef-Heron.
Egretta thula	Snowy Egret.
Egretta caerulea	Little Blue Heron.
Egretta tricolor	Tricolored Heron.
Egretta rufescens	Reddish Egret.
Bubulcus ibis	Cattle Egret.
Ardeola bacchus	Chinese Pond-Heron.
Butorides virescens	Green Heron.
Nycticorax nycticorax	Black-crowned Night-Heron.
Nycticorax caledonicus	Nankeen Night-Heron.
Nyctanassa violacea	Yellow-crowned Night-Heron.
Gorsachius goisagi	Japanese Night-Heron.
Gorsachius melanolophus	Malayan Night-Heron.
(C) Family Threskiornithidae	
(1) Subfamily Threskiornithinae	
Eudocimus albus	White Ibis.
Eudocimus ruber	Scarlet Ibis.
Plegadis falcinellus	Glossy Ibis.
Plegadis chihi	White-faced Ibis.
(2) Subfamily Plataleinae	
Platalea ajaja	Roseate Spoonbill.
(xvi) Order Carthartiformes	
Family Cathartidae	
Gymnogyps californianus	California Condor.
Coragyps atratus	Black Vulture.
Cathartes aura	Turkey Vulture.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
(xvii) Order Accipitriformes	
(A) Family Pandionidae	
Pandion haliaetus	Osprey.
(B) Family Accipitridae	
(1) Subfamily Elaninae	
Elanus leucurus	White-tailed Kite.
(2) Subfamily Gypaetinae	
Chondrohierax uncinatus	Hook-billed Kite.
Elanoides forficatus	Swallow-tailed Kite.
(3) Subfamily Accipitrinae	
Aquila chrysaetos	Golden Eagle.
Harpagus bidentatus	Double-toothed Kite.
Circus hudsonius	Northern Harrier.
Circus spilonotus	Eastern Marsh-Harrier.
Accipiter soloensis	Chinese Sparrowhawk.
Accipiter gularis	Japanese Sparrowhawk.
Accipiter striatus	Sharp-shinned Hawk.
Accipiter cooperii	Cooper's Hawk.
Accipiter gentilis	Northern Goshawk.
Milvus migrans	Black Kite.
Haliaeetus leucocephalus	Bald Eagle.
Haliaeetus albicilla	White-tailed Eagle.
Haliaeetus pelagicus	Steller's Sea-Eagle.
Ictinia mississippiensis	Mississippi Kite.
Butastur indicus	Gray-faced Buzzard.
Geranospiza caerulescens	Crane Hawk.
Rostrhamus sociabilis	Snail Kite.
Buteogallus anthracinus	Common Black Hawk.
Buteogallus urubitinga	Great Black Hawk.
Rupornis magnirostris	Roadside Hawk.
Parabuteo unicinctus	Harris's Hawk.
Geranoaetus albicaudatus	White-tailed Hawk.
Buteo plagiatus	Gray Hawk.
Buteo lineatus	Red-shouldered Hawk.
Buteo platypterus	Broad-winged Hawk.
Buteo solitarius	Hawaiian Hawk.
Buteo brachyurus	Short-tailed Hawk.
Buteo swainsoni	Swainson's Hawk.
Buteo albonotatus	Zone-tailed Hawk.
Buteo jamaicensis	Red-tailed Hawk.
Buteo lagopus	Rough-legged Hawk.
Buteo regalis	Ferruginous Hawk.
Buteo rufinus	Long-legged Buzzard.
(xviii) Order Strigiformes	
(A) Family Tytonidae	
Tyto alba	Barn Owl.
(B) Family Strigidae	
Otus sunia	Oriental Scops-Owl.
Psiloscops flammeolus	Flammulated Owl.
Gymnasio nudipes	Puerto Rican Owl.
Megascops trichopsis	Whiskered Screech-Owl.
Megascops kennicottii	Western Screech-Owl.
Megascops asio	Eastern Screech-Owl.
Bubo virginianus	Great Horned Owl.
Bubo scandiacus	Snowy Owl.
Surnia ulula	Northern Hawk Owl.
Glaucidium gnoma	Northern Pygmy-Owl.
Glaucidium brasilianum	Ferruginous Pygmy-Owl.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Micrathene whitneyi	Elf Owl.
Athene cunicularia	Burrowing Owl.
Strix occidentalis	Spotted Owl.
Strix varia	Barred Owl.
Strix virgata	Mottled Owl.
Strix nebulosa	Great Gray Owl.
Asio otus	Long-eared Owl.
Asio stygius	Stygian Owl.
Asio flammeus	Short-eared Owl.
Aegolius funereus	Boreal Owl.
Aegolius acadicus	Northern Saw-whet Owl.
Ninox japonica	Northern Boobook.
(xix) Order Trogoniformes	
Family Trogonidae	
Subfamily Trogoninae	
Trogon elegans	Elegant Trogon.
Euptilotis neoxenus	Eared Quetzal.
(xx) Order Upupiformes	
Family Upupidae	
Upupa epops	Eurasian Hoopoe.
(xxi) Order Coraciiformes	
Family Alcedinidae	
(1) Subfamily Alcedininae	
Alcedo atthis	Common Kingfisher.
(2) Subfamily Halcyoninae	
Todiramphus sacer	Pacific Kingfisher.
Todiramphus cinnamominus	Guam Kingfisher.
Todiramphus albicilla	Mariana Kingfisher.
(3) Subfamily Cerylinae	
Megaceryle torquata	Ringed Kingfisher.
Megaceryle alcyon	Belted Kingfisher.
Chloroceryle amazona	Amazon Kingfisher.
Chloroceryle americana	Green Kingfisher.
(xxii) Order Piciformes	
Family Picidae	
(1) Subfamily Jynginae	
Jynx torquilla	Eurasian Wryneck.
(2) Subfamily Picinae	
Melanerpes lewis	Lewis's Woodpecker.
Melanerpes portoricensis	Puerto Rican Woodpecker.
Melanerpes erythrocephalus	Red-headed Woodpecker.
Melanerpes formicivorus	Acorn Woodpecker.
Melanerpes uropygialis	Gila Woodpecker.
Melanerpes aurifrons	Golden-fronted Woodpecker.
Melanerpes carolinus	Red-bellied Woodpecker.
Sphyrapicus thyroideus	Williamson's Sapsucker.
Sphyrapicus varius	Yellow-bellied Sapsucker.
Sphyrapicus nuchalis	Red-naped Sapsucker.
Sphyrapicus ruber	Red-breasted Sapsucker.
Picoides dorsalis	American Three-toed Woodpecker.
Picoides arcticus	Black-backed Woodpecker.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Dendrocopos major	Great Spotted Woodpecker.
Dryobates pubescens	Downy Woodpecker.
Dryobates nuttallii	Nuttall's Woodpecker.
Dryobates scalaris	Ladder-backed Woodpecker.
Dryobates borealis	Red-cockaded Woodpecker.
Dryobates villosus	Hairy Woodpecker.
Dryobates albolarvatus	White-headed Woodpecker.
Dryobates arizonae	Arizona Woodpecker.
Colaptes auratus	Northern Flicker.
Colaptes chrysoides	Gilded Flicker.
Dryocopus pileatus	Pileated Woodpecker.
Campephilus principalis	Ivory-billed Woodpecker.
(xxiii) Order Falconiformes	
Family Falconidae	
(1) Subfamily Herpetotherinae	
Micrastur semitorquatus	Collared Forest-Falcon.
(2) Subfamily Falconinae	
Caracara plancus	Crested Caracara.
Falco tinnunculus	Eurasian Kestrel.
Falco sparverius	American Kestrel.
Falco vespertinus	Red-footed Falcon.
Falco amurensis	Amur Falcon.
Falco columbarius	Merlin.
Falco subbuteo	Eurasian Hobby.
Falco femoralis	Aplomado Falcon.
Falco rusticolus	Gyrfalcon.
Falco peregrinus	Peregrine Falcon.
Falco mexicanus	Prairie Falcon.
(xxiv) Order Passeriformes	
(A) Family Tityridae	
Tityra semifasciata	Masked Tityra.
Pachyramphus major	Gray-collared Becard.
Pachyramphus aglaiae	Rose-throated Becard.
(B) Family Tyrannidae	
(1) Subfamily Elaeniinae	
Camptostoma imberbe	Northern Beardless-Tyrannulet.
Myiopagis viridicata	Greenish Elaenia.
Elaenia martinica	Caribbean Elaenia.
Elaenia albiceps	White-crested Elaenia.
Elaenia parvirostris	Small-billed Elaenia.
(2) Subfamily Tyranninae	
Myiarchus tuberculifer	Dusky-capped Flycatcher.
Myiarchus cinerascens	Ash-throated Flycatcher.
Myiarchus nuttingi	Nutting's Flycatcher.
Myiarchus crinitus	Great Crested Flycatcher.
Myiarchus tyrannulus	Brown-crested Flycatcher.
Myiarchus sagrae	La Sagra's Flycatcher.
Myiarchus antillarum	Puerto Rican Flycatcher.
Pitangus sulphuratus	Great Kiskadee.
Myiozetetes similis	Social Flycatcher.
Myiodynastes luteiventris	Sulphur-bellied Flycatcher.
Legatus leucophaius	Piratic Flycatcher.
Empidonomus varius	Variegated Flycatcher.
Empidonomus aurantioatrocristatus	Crowned Slaty Flycatcher.
Tyrannus melancholicus	Tropical Kingbird.
Tyrannus couchii	Couch's Kingbird.
Tyrannus vociferans	Cassin's Kingbird.
Tyrannus crassirostris	Thick-billed Kingbird.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Tyrannus verticalis	Western Kingbird.
Tyrannus tyrannus	Eastern Kingbird.
Tyrannus dominicensis	Gray Kingbird.
Tyrannus caudifasciatus	Loggerhead Kingbird.
Tyrannus forficatus	Scissor-tailed Flycatcher.
Tyrannus savana	Fork-tailed Flycatcher.
(3) Subfamily Fluvicolinae	
Mitrephanes phaeocercus	Tufted Flycatcher.
Contopus cooperi	Olive-sided Flycatcher.
Contopus pertinax	Greater Pewee.
Contopus sordidulus	Western Wood-Pewee.
Contopus virens	Eastern Wood-Pewee.
Contopus caribaeus	Cuban Pewee.
Contopus hispaniolensis	Hispaniolan Pewee.
Contopus latirostris	Lesser Antillean Pewee.
Empidonax flaviventris	Yellow-bellied Flycatcher.
Empidonax virescens	Acadian Flycatcher.
Empidonax alnorum	Alder Flycatcher.
Empidonax traillii	Willow Flycatcher.
Empidonax minimus	Least Flycatcher.
Empidonax hammondii	Hammond's Flycatcher.
Empidonax wrightii	Gray Flycatcher.
Empidonax oberholseri	Dusky Flycatcher.
Empidonax affinis	Pine Flycatcher.
Empidonax difficilis	Pacific-slope Flycatcher.
Empidonax occidentalis	Cordilleran Flycatcher.
Empidonax fulvifrons	Buff-breasted Flycatcher.
Sayornis nigricans	Black Phoebe.
Sayornis phoebe	Eastern Phoebe.
Sayornis saya	Say's Phoebe.
Pyrocephalus rubinus	Vermilion Flycatcher.
(C) Family Vireonidae	
Vireo atricapilla	Black-capped Vireo.
Vireo griseus	White-eyed Vireo.
Vireo crassirostris	Thick-billed Vireo.
Vireo gundlachii	Cuban Vireo.
Vireo latimeri	Puerto Rican Vireo.
Vireo bellii	Bell's Vireo.
Vireo vicinior	Gray Vireo.
Vireo huttoni	Hutton's Vireo.
Vireo flavifrons	Yellow-throated Vireo.
Vireo cassinii	Cassin's Vireo.
Vireo solitarius	Blue-headed Vireo.
Vireo plumbeus	Plumbeous Vireo.
Vireo philadelphicus	Philadelphia Vireo.
Vireo gilvus	Warbling Vireo.
Vireo olivaceus	Red-eyed Vireo.
Vireo flavoviridis	Yellow-green Vireo.
Vireo altiloquus	Black-whiskered Vireo.
Vireo magister	Yucatan Vireo.
(D) Family Laniidae	
Lanius cristatus	Brown Shrike.
Lanius ludovicianus	Loggerhead Shrike.
Lanius borealis	Northern Shrike.
(E) Family Corvidae	
Perisoreus canadensis	Canada Jay.
Psilorhinus morio	Brown Jay.
Cyanocorax yncas	Green Jay.
Gymnorhinus cyanocephalus	Pinyon Jay.
Cyanocitta stelleri	Steller's Jay.
Cyanocitta cristata	Blue Jay.
Aphelocoma coerulescens	Florida Scrub-Jay.
Aphelocoma insularis	Island Scrub-Jay.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Aphelocoma californica	California Scrub-Jay.
Aphelocoma woodhouseii	Woodhouse's Scrub-Jay.
Aphelocoma wollweberi	Mexican Jay.
Nucifraga columbiana	Clark's Nutcracker.
Pica hudsonia	Black-billed Magpie.
Pica nuttalli	Yellow-billed Magpie.
Corvus monedula	Eurasian Jackdaw.
Corvus kubaryi	Mariana Crow.
Corvus brachyrhynchos	American Crow.
Corvus leucognaphalus	White-necked Crow.
Corvus imparatus	Tamaulipas Crow.
Corvus ossifragus	Fish Crow.
Corvus hawaiiensis	Hawaiian Crow.
Corvus cryptoleucus	Chihuahuan Raven.
Corvus corax	Common Raven.
(F) Family Remizidae	
Auriparus flaviceps	Verdin.
(G) Family Paridae	
Poecile carolinensis	Carolina Chickadee.
Poecile atricapillus	Black-capped Chickadee.
Poecile gambeli	Mountain Chickadee.
Poecile sclateri	Mexican Chickadee.
Poecile rufescens	Chestnut-backed Chickadee.
Poecile hudsonicus	Boreal Chickadee.
Poecile cinctus	Gray-headed Chickadee.
Baeolophus wollweberi	Bridled Titmouse.
Baeolophus inornatus	Oak Titmouse.
Baeolophus ridgwayi	Juniper Titmouse.
Baeolophus bicolor	Tufted Titmouse.
Baeolophus atricristatus	Black-crested Titmouse.
(H) Family Alaudidae	
Alauda arvensis	Eurasian Skylark.
Eremophila alpestris	Horned Lark.
(I) Family Acrocephalidae	
Arundinax aedon	Thick-billed Warbler.
Acrocephalus luscinius	Nightingale Reed Warbler.
Acrocephalus hiwae	Saipan Reed Warbler.
Acrocephalus nijoi	Aguiguan Reed Warbler.
Acrocephalus yamashinae	Pagan Reed Warbler.
Acrocephalus familiaris	Millerbird.
Acrocephalus schoenobaenus	Sedge Warbler.
Acrocephalus dumetorum	Blyth's Reed Warbler.
(J) Family Locustellidae	
Helopsaltes certhiola	Pallas's Grasshopper Warbler.
Helopsaltes ochotensis	Middendorff's Grasshopper Warbler.
Locustella lanceolata	Lanceolated Warbler.
Locustella fluviatilis	River Warbler.
(K) Family Hirundinidae	
Subfamily Hirundininae	
Riparia riparia	Bank Swallow.
Tachycineta bicolor	Tree Swallow.
Tachycineta cyaneoviridis	Bahama Swallow.
Tachycineta thalassina	Violet-green Swallow.
Tachycineta albilinea	Mangrove Swallow.
Pygochelidon cyanoleuca	Blue-and-white Swallow.
Stelgidopteryx serripennis	Northern Rough-winged Swallow.
Progne tapera	Brown-chested Martin.
Progne subis	Purple Martin.
Progne elegans	Southern Martin.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Progne chalybea	Gray-breasted Martin.
Progne cryptoleuca	Cuban Martin.
Progne dominicensis	Caribbean Martin.
Hirundo rustica	Barn Swallow.
Delichon urbicum	Common House-Martin.
Petrochelidon pyrrhonota	Cliff Swallow.
Petrochelidon fulva	Cave Swallow.
(L) Family Aegithalidae	
Psaltriparus minimus	Bushtit.
(M) Family Phylloscopidae	
Phylloscopus trochilus	Willow Warbler.
Phylloscopus collybita	Common Chiffchaff.
Phylloscopus sibilatrix	Wood Warbler.
Phylloscopus fuscatus	Dusky Warbler.
Phylloscopus proregulus	Pallas's Leaf Warbler.
Phylloscopus inornatus	Yellow-browed Warbler.
Phylloscopus borealis	Arctic Warbler.
Phylloscopus examinandus	Kamchatka Leaf Warbler.
(N) Family Sylviidae	
Sylvia curruca	Lesser Whitethroat.
Chamaea fasciata	Wrentit.
(O) Family Regulidae	
Corthylio calendula	Ruby-crowned Kinglet.
Regulus satrapa	Golden-crowned Kinglet.
(P) Family Bombycillidae	
Bombycilla garrulus	Bohemian Waxwing.
Bombycilla cedrorum	Cedar Waxwing.
(Q) Family Ptiliogonatidae	
Ptiliogonys cinereus	Gray Silky-flycatcher.
Phainopepla nitens	Phainopepla.
(R) Family Sittidae	
Subfamily Sittinae	
Sitta canadensis	Red-breasted Nuthatch.
Sitta carolinensis	White-breasted Nuthatch.
Sitta pygmaea	Pygmy Nuthatch.
Sitta pusilla	Brown-headed Nuthatch.
(S) Family Certhiidae	
Subfamily Certhiinae	
Certhia americana	Brown Creeper.
(T) Family Polioptilidae	
Polioptila caerulea	Blue-Gray Gnatcatcher.
Polioptila melanura	Black-tailed Gnatcatcher.
Polioptila californica	California Gnatcatcher.
Polioptila nigriceps	Black-capped Gnatcatcher.
(U) Family Troglodytidae	
Salpinctes obsoletus	Rock Wren.
Catherpes mexicanus	Canyon Wren.
Thryophilus sinaloa	Sinaloa Wren.
Campylorhynchus brunneicapillus	Cactus Wren.
Thryomanes bewickii	Bewick's Wren.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Thryothorus ludovicianus	Carolina Wren.
Troglodytes aedon	House Wren.
Troglodytes pacificus	Pacific Wren.
Troglodytes hiemalis	Winter Wren.
Cistothorus stellaris	Sedge Wren.
Cistothorus palustris	Marsh Wren.
(V) Family Mimidae	
Melanotis caerulescens	Blue Mockingbird.
Melanoptila glabrirostris	Black Catbird.
Dumetella carolinensis	Gray Catbird.
Margarops fuscatus	Pearly-eyed Thrasher.
Toxostoma curvirostre	Curve-billed Thrasher.
Toxostoma rufum	Brown Thrasher.
Toxostoma longirostre	Long-billed Thrasher.
Toxostoma bendirei	Bendire's Thrasher.
Toxostoma redivivum	California Thrasher.
Toxostoma lecontei	LeConte's Thrasher.
Toxostoma crissale	Crissal Thrasher.
Oreoscoptes montanus	Sage Thrasher.
Mimus gundlachii	Bahama Mockingbird.
Mimus polyglottos	Northern Mockingbird.
(W) Family Sturnidae	
Agropsar philippensis	Chestnut-cheeked Starling.
Spodiopsar cineraceus	White-cheeked Starling.
(X) Family Cinclidae	
Cinclus mexicanus	American Dipper.
(Y) Family Turdidae	
Sialia sialis	Eastern Bluebird.
Sialia mexicana	Western Bluebird.
Sialia currucoides	Mountain Bluebird.
Myadestes townsendi	Townsend's Solitaire.
Myadestes occidentalis	Brown-backed Solitaire.
Myadestes myadestinus	Kāmaʻo.
Myadestes lanaiensis	Oloma'o.
Myadestes obscurus	'Ōma'o.
Myadestes palmeri	Puaiohi.
Catharus aurantiirostris	Orange-billed Nightingale-Thrush.
Catharus mexicanus	Black-headed Nightingale-Thrush.
Catharus fuscescens	Veery.
Catharus minimus	Gray-cheeked Thrush.
Catharus bicknelli	Bicknell's Thrush.
Catharus ustulatus	Swainson's Thrush.
Catharus guttatus	Hermit Thrush.
Hylocichla mustelina	Wood Thrush.
Turdus obscurus	Eyebrowed Thrush.
Turdus eunomus	Dusky Thrush.
Turdus naumanni	Naumann's Thrush.
Turdus pilaris	Fieldfare.
Turdus iliacus	Redwing.
Turdus grayi	Clay-colored Thrush.
Turdus assimilis	White-throated Thrush.
Turdus rufopalliatus	Rufous-backed Robin.
Turdus migratorius	American Robin.
Turdus plumbeus	Red-legged Thrush.
Ixoreus naevius	Varied Thrush.
Ridgwayia pinicola	Aztec Thrush.
(Z) Family Muscicapidae	
Muscicapa griseisticta	Gray-streaked Flycatcher.
Muscicapa dauurica	Asian Brown Flycatcher.
Muscicapa striata	Spotted Flycatcher.
Muscicapa sibirica	Dark-sided Flycatcher.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Erithacus rubecula	European Robin.
Larvivora cyane	Siberian Blue Robin.
Larvivora sibilans	Rufous-tailed Robin.
Cyanecula svecica	Bluethroat.
Calliope calliope	Siberian Rubythroat.
Tarsiger cyanurus	Red-flanked Bluetail.
Ficedula narcissina	Narcissus Flycatcher.
Ficedula mugimaki	Mugimaki Flycatcher.
Ficedula albicilla	Taiga Flycatcher.
Phoenicurus phoenicurus	Common Redstart.
Saxicola maurus	Asian Stonechat.
Oenanthe oenanthe	Northern Wheatear.
Oenanthe pleschanka	Pied Wheatear.
Monticola solitarius	Blue Rock-Thrush.
(AA) Family Peucedramidae	
Peucedramus taeniatus	Olive Warbler.
(BB) Family Prunellidae	
Prunella montanella	Siberian Accentor.
(CC) Family Motacillidae	
Motacilla tschutschensis	Eastern Yellow Wagtail.
Motacilla citreola	Citrine Wagtail.
Motacilla cinerea	Gray Wagtail.
Motacilla alba	White Wagtail.
Anthus trivialis	Tree Pipit.
Anthus hodgsoni	Olive-backed Pipit.
Anthus gustavi	Pechora Pipit.
Anthus cervinus	Red-throated Pipit.
Anthus rubescens	American Pipit.
Anthus spragueii	Sprague's Pipit.
(DD) Family Fringillidae	
(1) Subfamily Fringillinae	
Fringilla coelebs	Common Chaffinch.
Fringilla montifringilla	Brambling.
(2) Subfamily Euphoniinae	
Chlorophonia musica	Antillean Euphonia.
(3) Subfamily Carduelinae	
Coccothraustes vespertinus	Evening Grosbeak.
Coccothraustes coccothraustes	Hawfinch.
Carpodacus erythrinus	Common Rosefinch.
Carpodacus roseus	Pallas's Rosefinch.
Melamprosops phaeosoma	Poʻouli.
Oreomystis bairdi	ʻAkikiki.
Paroreomyza maculata	Oʻahu ʻAlauahio.
Paroreomyza flammea	Kākāwahie.
Paroreomyza montana	Maui 'Alauahio.
Loxioides bailleui	Palila.
Telespiza cantans	Laysan Finch.
Telespiza ultima	Nihoa Finch.
Palmeria dolei	ʻAkohekohe.
Himatione fraithii	Laysan Honeycreeper.
Himatione sanguinea	ʻApapane.
Drepanis coccinea	ʻIʻiwi.
Psittirostra psittacea	ʻŌʻū.
Pseudonestor xanthophrys	Maui Parrotbill.
Hemignathus hanapepe	Kauai Nukupuʻu.
Hemignathus lucidus	Oʻahu Nukupuʻu.
Hemignathus affinis	Maui Nukupuʻu.
Hemignathus wilsoni	ʻAkiapolaʻau.
Akialoa stejnegeri	Kauai ʻAkialoa.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Akialoa ellisiana	Oʻahu ʻAkialoa.
Akialoa lanaiensis	Maui Nui ʼAkialoa.
Magumma parva	ʻAnianiau.
Chlorodrepanis virens	Hawaii ʻAmakihi.
Chlorodrepanis flava	Oʻahu ʻAmakihi.
Chlorodrepanis stejnegeri	Kauaʻi ʻAmakihi.
Loxops mana	Hawaii Creeper.
Loxops caeruleirostris	ʻAkekeʻe.
Loxops wolstenholmei	Oʻahu ʻAkepa.
Loxops ochraceus	Maui ʻAkepa.
Loxops coccineus	Hawaii ʻAkepa.
Pinicola enucleator	Pine Grosbeak.
Pyrrhula pyrrhula	Eurasian Bullfinch.
Leucosticte arctoa	Asian Rosy-Finch.
Leucosticte tephrocotis	Gray-crowned Rosy-Finch.
Leucosticte atrata	Black Rosy-Finch.
Leucosticte australis	Brown-capped Rosy-Finch.
Haemorhous mexicanus	House Finch.
Haemorhous purpureus	Purple Finch.
Haemorhous cassinii	Cassin's Finch.
Chloris sinica	Oriental Greenfinch.
Acanthis flammea	Common Redpoll.
Acanthis hornemanni	Hoary Redpoll.
Loxia curvirostra	Red Crossbill.
Loxia sinesciuris	Cassia Crossbill.
Loxia leucoptera	White-winged Crossbill.
Spinus spinus	Eurasian Siskin.
Spinus pinus	Pine Siskin.
Spinus psaltria	Lesser Goldfinch.
Spinus lawrencei	Lawrence's Goldfinch.
Spinus tristis	American Goldfinch.
(EE) Family Calcariidae	
Calcarius lapponicus	Lapland Longspur.
Calcarius ornatus	Chestnut-collared Longspur.
Calcarius pictus	Smith's Longspur.
Rhynchophanes mccownii	Thick-billed Longspur.
Plectrophenax nivalis	Snow Bunting.
Plectrophenax hyperboreus	McKay's Bunting.
(FF) Family Emberizidae	
Emberiza leucocephalos	Pine Bunting.
Emberiza chrysophrys	Yellow-browed Bunting.
Emberiza pusilla	Little Bunting.
Emberiza rustica	Rustic Bunting.
Emberiza elegans	Yellow-throated Bunting.
Emberiza aureola	Yellow-breasted Bunting.
Emberiza variabilis	Gray Bunting.
Emberiza pallasi	Pallas's Bunting.
Emberiza schoeniclus	Reed Bunting.
(GG) Family Passerellidae	
Peucaea carpalis	Rufous-winged Sparrow.
Peucaea botterii	Botteri's Sparrow.
Peucaea cassinii	Cassin's Sparrow.
Peucaea aestivalis	Bachman's Sparrow.
Ammodramus savannarum	Grasshopper Sparrow.
Arremonops rufivirgatus	Olive Sparrow.
Amphispizopsis quinquestriata	Five-striped Sparrow.
Amphispiza bilineata	Black-throated Sparrow.
Chondestes grammacus	Lark Sparrow.
Calamospiza melanocorys	Lark Bunting.
Spizella passerina	Chipping Sparrow.
Spizella pallida	Clay-colored Sparrow.
Spizella atrogularis	Black-chinned Sparrow.
Spizella pusilla	Field Sparrow.
Spizella breweri	Brewer's Sparrow.
Spizella wortheni	Worthen's Sparrow.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Passerella iliaca	Fox Sparrow.
Spizelloides arborea	American Tree Sparrow.
Junco hyemalis	Dark-eyed Junco.
Junco phaeonotus	Yellow-eyed Junco.
Zonotrichia leucophrys	White-crowned Sparrow.
Zonotrichia atricapilla	Golden-crowned Sparrow.
Zonotrichia querula	Harris's Sparrow.
Zonotrichia albicollis	White-throated Sparrow.
Artemisiospiza nevadensis	Sagebrush Sparrow.
Artemisiospiza belli	Bell's Sparrow.
Pooecetes gramineus	Vesper Sparrow.
Ammospiza leconteii	LeConte's Sparrow.
Ammospiza maritima	Seaside Sparrow.
Ammospiza nelsoni	Nelson's Sparrow.
Ammospiza caudacuta	Saltmarsh Sparrow.
Centronyx bairdii	Baird's Sparrow.
Centronyx henslowii	Henslow's Sparrow.
Passerculus sandwichensis	Savannah Sparrow.
Melospiza melodia	Song Sparrow.
Melospiza lincolnii	Lincoln's Sparrow.
Melospiza georgiana	Swamp Sparrow.
Melozone fusca	Canyon Towhee.
Melozone aberti	Abert's Towhee.
Melozone crissalis	California Towhee.
Aimophila ruficeps	Rufous-crowned Sparrow.
Pipilo chlorurus	Green-tailed Towhee.
Pipilo maculatus	Spotted Towhee.
Pipilo erythrophthalmus	Eastern Towhee.
(HH) Family Nesospingidae	
Nesospingus speculiferus	Puerto Rican Tanager.
(II) Family Spindalidae	
Spindalis zena	Western Spindalis.
Spindalis portoricensis	Puerto Rican Spindalis.
(JJ) Family Icteridae	
Icteria virens	Yellow-breasted Chat.
(1) Subfamily Xanthocephalinae	
Xanthocephalus xanthocephalus	Yellow-headed Blackbird.
(2) Subfamily Dolichonychinae	
Dolichonyx oryzivorus	Bobolink.
(3) Subfamily Sturnellinae	
Sturnella lilianae	Chihuahuan Meadowlark.
Sturnella magna	Eastern Meadowlark.
Sturnella neglecta	Western Meadowlark.
(4) Subfamily Icterinae	
Icterus portoricensis	Puerto Rican Oriole.
Icterus wagleri	Black-vented Oriole.
Icterus spurius	Orchard Oriole.
Icterus cucullatus	Hooded Oriole.
Icterus pustulatus	Streak-backed Oriole.
Icterus bullockii	Bullock's Oriole.
Icterus gularis	Altamira Oriole.
Icterus graduacauda	Audubon's Oriole.
Icterus galbula	Baltimore Oriole.
Icterus abeillei	Black-backed Oriole.
Icterus parisorum	Scott's Oriole.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
(5) Subfamily Agelaiinae	
Agelaius phoeniceus	Red-winged Blackbird.
Agelaius tricolor	Tricolored Blackbird.
Agelaius humeralis	Tawny-shouldered Blackbird.
Agelaius xanthomus	Yellow-shouldered Blackbird.
Molothrus bonariensis	Shiny Cowbird.
Molothrus aeneus	Bronzed Cowbird.
Molothrus ater	Brown-headed Cowbird.
Euphagus carolinus	Rusty Blackbird.
Euphagus cyanocephalus	Brewer's Blackbird.
Quiscalus quiscula	Common Grackle.
Quiscalus major	Boat-tailed Grackle.
Quiscalus mexicanus	Great-tailed Grackle.
Quiscalus niger	Greater Antillean Grackle.
(KK) Family Parulidae	
Seiurus aurocapilla	Ovenbird.
Helmitheros vermivorum	Worm-eating Warbler.
Parkesia motacilla	Louisiana Waterthrush.
Parkesia noveboracensis	Northern Waterthrush.
Vermivora bachmanii	Bachman's Warbler.
Vermivora chrysoptera	Golden-winged Warbler.
Vermivora cyanoptera	Blue-winged Warbler.
Mniotilta varia	Black-and-white Warbler.
Protonotaria citrea	Prothonotary Warbler.
Limnothlypis swainsonii	Swainson's Warbler.
Oreothlypis superciliosa	Crescent-chested Warbler.
Leiothlypis peregrina	Tennessee Warbler.
Leiothlypis celata	Orange-crowned Warbler.
Leiothlypis crissalis	Colima Warbler.
Leiothlypis luciae	Lucy's Warbler.
Leiothlypis ruficapilla	Nashville Warbler.
Leiothlypis virginiae	Virginia's Warbler.
Oporornis agilis	Connecticut Warbler.
Geothlypis poliocephala	Gray-crowned Yellowthroat.
Geothlypis tolmiei	MacGillivray's Warbler.
Geothlypis philadelphia	Mourning Warbler.
Geothlypis formosa	Kentucky Warbler.
Geothlypis trichas	Common Yellowthroat.
Setophaga angelae	Elfin-woods Warbler.
Setophaga citrina	Hooded Warbler.
Setophaga ruticilla	American Redstart.
Setophaga kirtlandii	Kirtland's Warbler.
Setophaga tigrina	Cape May Warbler.
Setophaga cerulea	Cerulean Warbler.
Setophaga americana	Northern Parula.
Setophaga pitiayumi	Tropical Parula.
Setophaga magnolia	Magnolia Warbler.
Setophaga castanea	Bay-breasted Warbler.
Setophaga fusca	Blackburnian Warbler.
Setophaga petechia	Yellow Warbler.
Setophaga pensylvanica	Chestnut-sided Warbler.
Setophaga striata	Blackpoll Warbler.
Setophaga caerulescens	Black-throated Blue Warbler.
Setophaga palmarum	Palm Warbler.
Setophaga pinus	Pine Warbler.
Setophaga coronata	Yellow-rumped Warbler.
Setophaga dominica	Yellow-throated Warbler.
Setophaga discolor	Prairie Warbler.
Setophaga adelaidae	Adelaide's Warbler.
Setophaga graciae	Grace's Warbler.
Setophaga nigrescens	Black-throated Gray Warbler.
Setophaga townsendi	Townsend's Warbler.
Setophaga occidentalis	Hermit Warbler.
Setophaga chrysoparia	Golden-cheeked Warbler.
Setophaga virens	Black-throated Green Warbler.
Basileuterus lachrymosus	Fan-tailed Warbler.
Basileuterus rufifrons	Rufous-capped Warbler.
Basileuterus culicivorus	Golden-crowned Warbler.

TABLE 2 TO PARAGRAPH (c)(2)—TAXONOMIC LISTING OF BIRDS PROTECTED BY THE MIGRATORY BIRD TREATY ACT—Continued

Species scientific name	Species common name
Cardellina canadensis	Canada Warbler.
Cardellina pusilla	Wilson's Warbler.
Cardellina rubrifrons	Red-faced Warbler.
Myioborus pictus	Painted Redstart.
Myioborus miniatus	Slate-throated Redstart.
(LL) Family Cardinalidae	
Piranga flava	Hepatic Tanager.
Piranga rubra	Summer Tanager.
Piranga olivacea	Scarlet Tanager.
Piranga ludoviciana	Western Tanager.
Piranga bidentata	Flame-colored Tanager.
Rhodothraupis celaeno	Crimson-collared Grosbeak.
Cardinalis cardinalis	Northern Cardinal.
Cardinalis sinuatus	Pyrrhuloxia.
Pheucticus chrysopeplus	Yellow Grosbeak.
Pheucticus ludovicianus	Rose-breasted Grosbeak.
Pheucticus melanocephalus	Black-headed Grosbeak.
Cyanocompsa parellina	Blue Bunting.
Passerina caerulea	Blue Grosbeak.
Passerina amoena	Lazuli Bunting.
Passerina cyanea	Indigo Bunting.
Passerina versicolor	Varied Bunting.
Passerina ciris	Painted Bunting.
Spiza americana	Dickcissel.
(MM) Family Thraupidae	
(1) Subfamily Dacninae	
Cyanerpes cyaneus	Red-legged Honeycreeper.
(2) Subfamily Coerebinae	
Coereba flaveola	Bananaquit.
Tiaris olivaceus	Yellow-faced Grassquit.
Melopyrrha portoricensis	Puerto Rican Bullfinch.
Melanospiza bicolor	Black-faced Grassquit.
(3) Subfamily Sporophilinae	
Sporophila morelleti	Morelet's Seedeater.

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

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

■ 4. Amend § 17.11, in paragraph (h), the List of Endangered and Threatened Wildlife, under BIRDS, by:

■ a. Revising the entries for ''Caracara, crested, (Audubon's) [FL DPS]'', ''Crane, Mississippi sandhill'', ''Nightjar, Puerto Rican'', and ''Pigeon, Puerto Rican plain'';

■ b. Removing the entries for ''Rail, California clapper'' and ''Rail, light-footed clapper'';

■ c. Adding, in alphabetical order, entries for ''Rail, California Ridgway's'' and ''Rail, light-footed Ridgway's''; and

■ d. Revising the entries for ''Sparrow, Cape Sable seaside'', ''Tern, California least'', and ''Towhee, Inyo California''.

The revisions and additions read as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
*	*	*	*	*
BIRDS				
*	*	*	*	*
Caracara, crested, (Audubon's) [FL DPS].	*Caracara plancus audubonii*	U.S.A. (FL)	T	52 FR 25229, 7/6/1987.

Common name	Scientific name	Where listed	Status	Listing citations and applicable rules
* *	*	*	*	* *
Crane, Mississippi sandhill	*Antigone canadensis pulla*	Wherever found	E	38 FR 14678, 6/4/1973; 50 CFR 17.95(b).[CH]
* *	*	*	*	* *
Nightjar, Puerto Rican	*Antrostomus noctitherus*	Wherever found	E	38 FR 14678, 6/4/1973.
* *	*	*	*	* *
Pigeon, Puerto Rican plain	*Patagioenas inornata wetmorei.*	Wherever found	E	35 FR 16047, 10/13/1970.
* *	*	*	*	* *
Rail, California Ridgway's	*Rallus obsoletus obsoletus*	Wherever found	E	35 FR 16047, 10/13/1970.
* *	*	*	*	* *
Rail, light-footed Ridgway's	*Rallus obsoletus levipes*	U.S.A. only	E	34 FR 5034, 3/8/1969; 35 FR 16047, 10/13/1970.
* *	*	*	*	* *
Sparrow, Cape Sable seaside	*Ammospiza maritima mirabilis*	Wherever found	E	32 FR 4001, 3/11/1967; 50 CFR 17.95(b).[CH]
* *	*	*	*	* *
Tern, California least	*Sternula antillarum browni*	Wherever found	E	35 FR 16047, 10/13/1970; 35 FR 8491, 6/2/1970.
* *	*	*	*	* *
Towhee, Inyo California	*Melozone crissalis eremophilus.*	Wherever found	T	52 FR 28780, 8/3/1987; 50 CFR 17.95(b).[CH]
* *	*	*	*	* *

■ 5. Amend § 17.95, in paragraph (b), by
■ a. Revising the headings for ''Mississippi Sandhill Crane (*Grus canadensis pulla*)'' and ''Cape Sable Seaside Sparrow (*Ammodramus maritimus mirabilis*)''; and
■ b. Removing the heading ''Inyo Brown Towhee (*Pipilo fuscus eremophilus*)'' and adding in its place a heading for ''Inyo California Towhee (*Melozone crissalis eremophilus*)''.

The revisions and addition read as follows:

§ 17.95 Critical habitat—fish and wildlife.

(b) * * *

MISSISSIPPI SANDHILL CRANE
(*Antigone canadensis pulla*)

* * * * *

CAPE SABLE SEASIDE SPARROW
(*Ammospiza maritima mirabilis*)

* * * * *

INYO CALIFORNIA TOWHEE
(*Melozone crissalis eremophilus*)

* * * * *

PART 21—MIGRATORY BIRD PERMITS

■ 6. The authority citation for part 21 continues to read as follows:

Authority: 16 U.S.C. 703–712.

§ 21.123 [Amended]

■ 7. Amend § 21.123, in the introductory text of paragraph (a), by removing the words ''(*Phalacrocorax auritus*)'' and adding in their place the words ''(*Nannopterum auritum*)''.

Shannon A. Estenoz,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2023–15551 Filed 7–28–23; 8:45 am]

BILLING CODE 4333–15–P

Proposed Rules

Federal Register
Vol. 88, No. 145
Monday, July 31, 2023

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

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1206

[Doc. No. AMS–SC–21–0101]

Adjustments to Mango Board Representation; Withdrawal of Proposed Rule

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Agricultural Marketing Service (AMS) withdraws a proposed rule recommended by the National Mango Board (Board) that would have adjusted the Mango Promotion, Research, and Information Order (Order) to allocate the seven foreign producer Board seats to the top five mango exporting countries, based on mango volume exported to the United States, with an additional seat allocated to the top exporting country, and one at-large seat. In addition, the proposal would have required no more than one Board member be employed by or be affiliated with the same company. After reviewing and considering the comments received, the proposed rule is being withdrawn.

DATES: The proposed rule published at 87 FR 65683 on November 1, 2022, is withdrawn as of July 31, 2023.

FOR FURTHER INFORMATION CONTACT: George Webster, Marketing Specialist, Mid Atlantic Branch, Market Development Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW, Room 1406–S, Stop 0244, Washington, DC 20250–0244; telephone: (202) 365–4172; or email: *George.Webster@usda.gov.*

SUPPLEMENTARY INFORMATION: This withdrawal is issued under the Order (7 CFR part 1206). The Order is authorized under the Commodity Promotion, Research, and Information Act of 1996 (Act) (7 U.S.C. 7411–7425). The Board administers the Order and is comprised of 18 members, including eight importers, two domestic producers, one first handler, and seven foreign producers.

This action withdraws a proposed rule published in the **Federal Register** on November 1, 2022 (87 FR 65683), to revise several sections of the Order's representation requirements. The proposed rule's comment period was open from the publication date of November 1, 2022, to January 3, 2023. The proposed rule would have allocated the seven foreign producer Board seats to the top five mango exporting countries, based on mango volume exported to the United States, with an additional seat allocated to the top exporting country, and one at-large seat. In addition, the proposal would have required no more than one Board member be employed by or be affiliated with the same company. The proposed changes were intended to modify the Order's requirements to ensure that the countries exporting the most mangos to the U.S. would be represented on the Board, and to broaden the diversity of members serving on the Board.

Comments Received

During the proposed rule's 60-day comment period, AMS received 58 comments, which may be viewed on the internet at *https://www.regulations.gov.* Of the comments received, 32 comments (roughly 55%) opposed the proposed rule, 24 comments (roughly 41%) were in favor of the proposed rule, and two comments (roughly 3%) were non-substantive with regard to the merits of the proposal.

Comments in Opposition: During the public comment period, commenters identified anticipated adverse effects to Mexico, the largest country based on mango volume imported into the United States (62.9 percent average from 2019–2021). Approximately 50 percent of all comments cited the proposed rule's negative impact to Mexico's ability to have proportionate representation on the Board. These commenters claimed that the proposed rule, if effectuated, would give countries with smaller import volume guaranteed representation, thereby limiting the seats available for Mexican foreign producers.

AMS also reviewed comments opposing the proposed change that would require no more than one Board member be employed by or be affiliated with the same company. Comments expressed concern that many mango importers work with a multitude of companies and growers throughout the year, and the proposed changes would greatly restrict the pool of candidates to serve on the Board. Commenters also explained that the Board has had more than one member from a company serve concurrently multiple times in the past, and there has yet to be any conflict arising from the situation. One comment expressed concern that the proposed change would place additional burden on the Board's domestic representation, and limiting how many representatives from one company or related companies can serve on the Board concurrently would further shrink an already limited pool of candidates.

Comments in Support: In general, 24 commenters were in favor of the proposed rule, and agreed that the changes would allow for a more balanced foreign producer representation on the Board and provide opportunities for a more diverse group of members to serve. One commenter explained that each of the top five importing countries are the main supplier of mangoes to the United States at different times of the year, and by having broad representation from those countries on the Board, the entire industry could benefit from gaining the unique perspective of that region.

Also, one commenter mentioned that limiting membership to one member per affiliated company would guard against company-centric voting blocks that could potentially benefit one company more than the entire industry. Another comment said that the Board should further limit membership, so no two members of the same family can serve concurrently.

Non-Substantive Comments: Two comments received during the public comment period were non-substantive with regard to the merits of the proposal and were therefore not considered during the review process.

After reviewing and considering the comments submitted by stakeholders that are regulated by the Order, AMS determined that the concerns raised were significant enough to not move forward with the proposed rule at this time and to direct the Board to conduct further outreach. Accordingly, the proposed rule to adjust the National Mango Board's representation in the Order, published in the **Federal Register**

on November 1, 2022 (87 FR 65683), is hereby withdrawn.

List of Subjects in 7 CFR Part 1206

Administrative practice and procedure, Advertising, Consumer information, Mango promotion, Marketing agreements, Reporting and recording requirements.

Authority: 7 U.S.C. 7411–7425 and 7 U.S.C. 7401.

Erin Morris,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2023–16196 Filed 7–28–23; 8:45 am]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

10 CFR Part 72

[NRC–2023–0085]

RIN 3150–AK99

List of Approved Spent Fuel Storage Casks: NAC International, Inc. MAGNASTOR® Storage System, Certificate of Compliance No. 1031, Amendment Nos. 11 and 12 and Revisions to Amendment Nos. 0 Through 9

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is proposing to amend its spent fuel regulations by revising the NAC International, Inc. MAGNASTOR® Storage System listing within the ''List of approved spent fuel storage casks'' to include Amendment Nos. 11 and 12 and revisions to Amendment Nos. 0 through 9 to Certificate of Compliance No. 1031. Amendment No. 11 amends the certificate of compliance to add a new concrete cask, transfer cask, fuel baskets and revised contents. Amendment No. 11 also adds a definition for the concrete cask lid, revises the definition for the concrete cask to exclude the lid, adds a definition for the storage cask, and provides alternate fabrication criteria and techniques for the concrete cask lid. Amendment No. 12 and revisions to Amendment Nos. 0 through 9 add definitions for the storage cask and concrete cask lid, revise the definition of the concrete cask, and provide alternate fabrication criteria and techniques for the concrete cask lid to the certificate of compliance.

DATES: Submit comments by August 30, 2023. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2023–0085, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Bernard White, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–6577, email: *Bernard.White@nrc.gov* and Irene Wu, Office of Nuclear Materials Safety and Safeguards, telephone: 301–415–1951, email: *Irene.Wu@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Obtaining Information and Submitting Comments
II. Rulemaking Procedure
III. Background
IV. Plain Writing
V. Availability of Documents

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2023–0085 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

- *Federal Rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0085. Address questions about NRC dockets to Dawn Forder, telephone: 301–415–3407, email: *Dawn.Forder@nrc.gov.* For technical questions contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time, Monday through Friday, except Federal holidays.

B. Submitting Comments

Please include Docket ID NRC–2023–0085 in your comment submission. The NRC requests that you submit comments through the Federal rulemaking website at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Rulemaking Procedure

Because the NRC considers this action to be non-controversial, the NRC is publishing this proposed rule concurrently with a direct final rule in the Rules and Regulations section of this issue of the **Federal Register**. The direct final rule will become effective on October 16, 2023. However, if the NRC receives any significant adverse comment by August 30, 2023, then the NRC will publish a document that withdraws the direct final rule. If the

direct final rule is withdrawn, the NRC will address the comments in a subsequent final rule. In general, absent significant modifications to the proposed revisions requiring republication, the NRC will not initiate a second comment period on this action in the event the direct final rule is withdrawn.

A significant adverse comment is a comment where the commenter explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. A comment is adverse and significant if:

(1) The comment opposes the rule and provides a reason sufficient to require a substantive response in a notice-and-comment process. For example, a substantive response is required when:

(a) The comment causes the NRC to reevaluate (or reconsider) its position or conduct additional analysis;

(b) The comment raises an issue serious enough to warrant a substantive response to clarify or complete the record; or

(c) The comment raises a relevant issue that was not previously addressed or considered by the NRC.

(2) The comment proposes a change or an addition to the rule, and it is apparent that the rule would be ineffective or unacceptable without incorporation of the change or addition.

(3) The comment causes the NRC to make a change (other than editorial) to the rule.

For a more detailed discussion of the proposed rule changes and associated analyses, see the direct final rule published in the Rules and Regulations section of this issue of the **Federal Register**.

III. Background

Section 218(a) of the Nuclear Waste Policy Act of 1982, as amended, requires that ''[t]he Secretary [of the Department of Energy] shall establish a demonstration program, in cooperation with the private sector, for the dry storage of spent nuclear fuel at civilian nuclear power reactor sites, with the objective of establishing one or more technologies that the [Nuclear Regulatory] Commission may, by rule, approve for use at the sites of civilian nuclear power reactors without, to the maximum extent practicable, the need for additional site-specific approvals by the Commission.'' Section 133 of the Nuclear Waste Policy Act states, in part, that ''[t]he Commission shall, by rule, establish procedures for the licensing of any technology approved by the Commission under Section 219(a) [sic: 218(a)] for use at the site of any civilian nuclear power reactor.''

To implement this mandate, the Commission approved dry storage of spent nuclear fuel in NRC-approved casks under a general license by publishing a final rule that added a new subpart K in part 72 of title 10 of the *Code of Federal Regulations* (10 CFR) entitled ''General License for Storage of Spent Fuel at Power Reactor Sites'' (55 FR 29181; July 18, 1990). This rule also established a new subpart L in 10 CFR part 72 entitled ''Approval of Spent Fuel Storage Casks,'' which contains procedures and criteria for obtaining NRC approval of spent fuel storage cask designs. The NRC subsequently issued a final rule on November 21, 2008 (73 FR 70587), that approved the NAC International, Inc. MAGNASTOR® Storage System design and added it to the list of NRC-approved cask designs in § 72.214 as Certificate of Compliance No. 1031.

IV. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on the proposed rule with respect to clarity and effectiveness of the language used.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	ADAMS accession No./ **Federal Register** citation
Documents Related to Initial Certificate (Amendment No. 0), Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2	ML22220A151.
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A152.
Proposed Certificate of Compliance No. 1031, Amendment No. 0, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A154.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110
Documents Related to Amendment No. 1, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2	ML22220A156.
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A157.
Proposed Certificate of Compliance No. 1031, Amendment No. 1, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A158.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.

Document	ADAMS accession No./ **Federal Register** citation
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 2, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2	ML22220A159.
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A160.
Proposed Certificate of Compliance No. 1031, Amendment No. 2, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A161.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 3, Revision 2	
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2	ML22220A163.
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A164.
Proposed Certificate of Compliance No. 1031, Amendment No. 3, Revision 2, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A165.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 4, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1	ML22220A166.
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A167.
Proposed Certificate of Compliance No. 1031, Amendment No. 4, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A168.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 5, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1	ML22220A169.
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A170.
Proposed Certificate of Compliance No. 1031, Amendment No. 5, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A171.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 6, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1	ML22220A172.
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A173.
Proposed Certificate of Compliance No. 1031, Amendment No. 6, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A174.

Document	ADAMS accession No./ **Federal Register** citation
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 7, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1	ML22220A175.
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A176.
Proposed Certificate of Compliance No. 1031, Amendment No. 7, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A177.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 8, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1	ML22220A178.
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A179.
Proposed Certificate of Compliance No. 1031, Amendment No. 8, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A180.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment Nos. 0–8.	ML22227A174.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 9, Revision 1	
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1	ML22220A181.
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A182.
Proposed Certificate of Compliance No. 1031, Amendment No. 9, Revision 1, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A183.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Revision to Amendment No. 9.	ML22220A184.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
NAC International, MAGNASTOR® Cask System Users CoC Amendments 0 thru 9 Intent to Adopt Letters, dated August 4, 2022.	ML22216A110.
Documents Related to Amendment No. 11	
Proposed Certificate of Compliance No. 1031, Amendment No. 11	ML22220A185.
Proposed Certificate of Compliance No. 1031, Amendment No. 11, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A186.
Proposed Certificate of Compliance No. 1031, Amendment No. 11, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A187.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Amendment No. 11.	ML22220A188.
NAC International, Submission of a Request to Amend Certificate of Compliance No. 1031 for the NAC International MAGNASTOR® Cask System, Docket No. 72–1031, dated July 14, 2020.	ML20210M079 (package).
NAC International, Submission of RAI Responses for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated August 23, 2021.	ML21242A053 (package).
NAC International, Submission of Supplemental Information to the RAI for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated January 11, 2022.	ML22018A059.

Document	ADAMS accession No./ **Federal Register** citation
NAC International, Submission of Supplemental Information to the RAI for the NAC International MAGNASTOR® Cask System Amendment No. 11, Docket No. 72–1031, dated July 15, 2022.	ML22196A022 (package).
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
Documents Related to Amendment No. 12	
Proposed Certificate of Compliance No. 1031, Amendment No. 12	ML22220A189.
Proposed Certificate of Compliance No. 1031, Amendment No. 12, Appendix A: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A190.
Proposed Certificate of Compliance No. 1031, Amendment No. 12, Appendix B: Technical Specifications for the MAGNASTOR® Storage System.	ML22220A191.
Preliminary Safety Evaluation Report for NAC International, Inc. MAGNASTOR® Storage System: Certificate of Compliance No. 1031, Docket No. 72–1031, Amendment No. 12.	ML22220A192.
NAC International, Submission of an Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated January 24, 2022.	ML22024A374.
NAC International, Supplement to NAC's Amendment Request for the NAC International MAGNASTOR® Cask System Amendment No. 12, dated March 18, 2022.	ML22077A769.
NAC International, Submittal of RAI Response to Amendment Request for NAC International MAGNASTOR® Cask System Amendment No. 12, dated April 18, 2022.	ML22108A197.
Other Documents	
User Need Memorandum for Amendment Nos. 11 and 12, and Revision to Amendment Nos. 0 through 9 for the MAGNASTOR® Storage System, dated March 7, 2023.	ML22220A150.
Final Rule, "Storage of Spent Fuel in NRC-Approved Storage Casks at Power Reactor Sites," published July 18, 1990.	55 FR 29181.
Final Rule, "List of Approved Spent Fuel Storage Casks: MAGNASTOR Addition," published November 21, 2008	73 FR 70587.
Revision to Policy Statement, "Agreement State Program Policy Statement; Correction," published October 18, 2017.	82 FR 48535.
Presidential Memorandum, "Plain Language in Government Writing," published June 10, 1998	63 FR 31885.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2023–0085. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2023–0085); (2) click the "Subscribe" link; and (3) enter an email address and click on the "Subscribe" link.

Dated: July 18, 2023.

For the Nuclear Regulatory Commission.

Daniel H. Dorman,

Executive Director for Operations.

[FR Doc. 2023–16145 Filed 7–28–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2023–1637; Project Identifier MCAI–2023–00184–E]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce Deutschland Ltd & Co KG Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for all Rolls-Royce Deutschland Ltd & Co KG (RRD) Model Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 engines. This proposed AD was prompted by reports of cracking and separation of certain low-pressure turbine (LPT) stage 1 blade assemblies. This proposed AD would require initial and repetitive inspections of affected LPT stage 1 blade assemblies for cracking or separation and, depending on the results of the inspections, reduction of the inspection interval or replacement of the LPT stage 1 blade set and disk, as specified in a European Union Aviation Safety Agency (EASA) AD, which is proposed for incorporation by reference (IBR). The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by September 14, 2023.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2023–1637; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory

continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For EASA service information material identified in this NPRM, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this material on the EASA website at *ad.easa.europa.eu.*
- You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

FOR FURTHER INFORMATION CONTACT: Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2023–1637; Project Identifier MCAI–2023–00184–E'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD 2023–0027, dated January 31, 2023 (EASA AD 2023–0027) (referred to after this as the MCAI), to address an unsafe condition for all RRD Model Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2 and Trent 1000–L2 engines. The MCAI states that manufacturer inspections detected cracking and separation of blade pairs in the weld region of certain LPT stage 1 blade assemblies. A blade assembly consists of a pair of blades welded together at the outer shroud. There are 85 LPT stage 1 blade assemblies in one set. Such cracking and separation could cause failure of affected parts and damage to the LPT module.

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2023–1637.

Related Service Information Under 1 CFR Part 51

The FAA reviewed EASA AD 2023–0027, which specifies procedures for inspection of affected LPT stage 1 blade assemblies and replacement of the LPT stage 1 blade set and disk. EASA AD 2023–0027 also specifies a reduction of the repetitive inspection intervals if cracking or separation is detected and meets certain criteria. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in **ADDRESSES**.

FAA's Determination

These products have been approved by the aviation authority of another country and are approved for operation in the United States. Pursuant to the FAA's bilateral agreement with this State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI described above. The FAA is issuing this NPRM after determining that the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in the MCAI described previously, except for any differences identified as exceptions in the regulatory text of this proposed.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has since coordinated with other manufacturers and CAAs to use this process. As a result, the FAA proposes to incorporate by reference EASA AD 2023–0027 in the FAA final rule. This proposed AD would, therefore, require compliance with EASA AD 2023–0027 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Using common terms that are the same as the heading of a particular section in the EASA AD does not mean that operators need comply only with that section. For example, where the AD requirement refers to ''all required actions within the compliance times,'' compliance with this AD requirement is not limited to the section titled ''Required Action(s) and Compliance Time(s)'' in EASA AD 2023–0027. Service information required by the EASA AD for compliance will be available at *regulations.gov* by searching for and locating Docket No. FAA–2023–1637 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 26 engines installed on airplanes of U.S. Registry.

The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspect LPT stage 1 blade assemblies	4 work-hours × $85 per hour = $340	$0	$340	$8,840

The FAA estimates the following costs to do any necessary replacements that would be required based on the results of the proposed inspection. The agency has no way of determining the number of aircraft that might need these replacements:

ON-CONDITION COSTS

Action	Labor cost	Parts cost	Cost per product
Replace LPT stage 1 blade set and disk	4 work-hours × $85 per hour = $340	$720,000	$720,340

Authority for This Rulemaking

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

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

Regulatory Findings

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

For the reasons discussed above, I certify this proposed regulation:

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

(2) Would not affect intrastate aviation in Alaska, and

(3) Would not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Rolls-Royce Deutschland Ltd. & Co. KG: Docket No. FAA–2023–1637; Project Identifier MCAI–2023–00184–E.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 14, 2023.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce Deutschland Ltd & Co KG (RRD) Model Trent 1000–A2, Trent 1000–AE2, Trent 1000–C2, Trent 1000–CE2, Trent 1000–D2, Trent 1000–E2, Trent 1000–G2, Trent 1000–H2, Trent 1000–J2, Trent 1000–K2, and Trent 1000–L2 engines.

(d) Subject

Joint Aircraft Service Component (JASC) Code 7250, Turbine Section.

(e) Unsafe Condition

This AD was prompted by reports of cracking and separation of certain low-pressure turbine (LPT) stage 1 blade assemblies. The FAA is issuing this AD to prevent failure of the LPT stage 1 blades. The unsafe condition, if not addressed, could result in high energy debris release, damage to the airplane, and reduced control of the airplane.

(f) Compliance

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

(g) Required Actions

Except as specified in paragraphs (h) and (i) of this AD: Perform all required actions within the compliance times specified in, and in accordance with, European Union Aviation Safety Agency AD 2023–0027, dated January 31, 2023 (EASA AD 2023–0027).

(h) Exceptions to EASA AD 2023–0027

(1) Where EASA AD 2023–0027 specifies compliance from its effective date, this AD requires using the effective date of this AD.

(2) This AD does not adopt the Remarks paragraph of EASA AD 2023–0027.

(3) Where the service information referenced in EASA AD 2023–0027 specifies discarding the removed LP turbine stage 1 blade set, this AD requires removing the affected part from service.

(4) Where the service information referenced in EASA AD 2023–0027 specifies to quarantine the removed LP turbine stage 1 rotor disc, this AD requires removing the affected part from service.

(i) No Reporting Requirement

Although the service information referenced in EASA AD 2023–0027 specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, AIR–520, Continued Operational Safety Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the branch office, send it to the attention of the person identified in

paragraph (k) of this AD and email to: *ANE-AD-AMOC@faa.gov.*

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

(k) Additional Information

For more information about this AD, contact Sungmo Cho, Aviation Safety Engineer, FAA, 2200 South 216th Street, Des Moines, WA 98198; phone: (781) 238–7241; email: *sungmo.d.cho@faa.gov.*

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) European Union Aviation Safety Agency AD 2023–0027, dated January 31, 2023.

(ii) [Reserved]

(3) For EASA AD 2023–0027, contact EASA, Konrad-Adenauer-Ufer 3, 50668 Cologne, Germany; phone: +49 221 8999 000; email: *ADs@easa.europa.eu;* website: *easa.europa.eu.* You may find this EASA AD on the EASA website at *ad.easa.europa.eu.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 1200 District Avenue, Burlington, MA 01803. For information on the availability of this material at the FAA, call (817) 222–5110.

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

Issued on July 21, 2023.

Victor Wicklund,

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

[FR Doc. 2023–15910 Filed 7–28–23; 8:45 am]

BILLING CODE 4910–13–P

FEDERAL TRADE COMMISSION

16 CFR Part 465

RIN 3084–AB76

Trade Regulation Rule on the Use of Consumer Reviews and Testimonials

AGENCY: Federal Trade Commission.

ACTION: Notice of proposed rulemaking; request for public comment.

SUMMARY: The Federal Trade Commission (''FTC or ''Commission'') commences a rulemaking to promulgate a trade regulation rule entitled ''Rule on the Use of Consumer Reviews and Testimonials,'' which would prohibit certain specified unfair or deceptive acts or practices involving consumer reviews or testimonials. The Commission finds such practices to be prevalent based on the comments it received in response to an advance notice of proposed rulemaking and other information discussed in this publication. The Commission now solicits written comment, data, and arguments concerning the utility and scope of the proposed trade regulation rule to prohibit the specified unfair or deceptive acts or practices.

DATES: Comments must be received on or before September 29, 2023.

ADDRESSES: Interested parties may file a comment online or on paper by following the instructions in the Comment Submissions part of the **SUPPLEMENTARY INFORMATION** section below. Write ''Reviews and Testimonials NPRM, R311003'' on your comment and file your comment online at *https://www.regulations.gov.* If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex F), Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Michael Ostheimer, Attorney, Federal Trade Commission, Bureau of Consumer Protection, Advertising Practices Division, (202) 326–2699, *mostheimer@ftc.gov.*

SUPPLEMENTARY INFORMATION: The Commission invites interested parties to submit data, views, and arguments on the proposed Rule on the Use of Consumer Reviews and Testimonials (''proposed Rule'') and, specifically, on the questions set forth in Section X of this notice of proposed rulemaking (''NPRM''). The comment period will remain open until September 29, 2023.[1] To the extent practicable, all comments will be available on the public record and posted at the docket for this rulemaking on *https://www.regulations.gov.* If interested parties request to present their position orally, the Commission will hold an informal hearing, as specified in Section 18(c) of the FTC Act, 15 U.S.C. 57a(c). Persons interested in making a presentation at an informal hearing must file a comment expressly requesting a hearing in response to this publication, containing a statement identifying their interests in the proceeding and any proposals to add disputed issues of material fact necessary to be resolved during an informal hearing. The comment should describe why the person thinks the informal hearing is warranted and how they would participate, and include a summary of their expected testimony. Interested persons' comments may also, without requesting an informal hearing, expressly request to speak at any informal hearing that is held, which may happen if another commenter requests an informal hearing or if the Commission on its own elects to hold one. If an informal hearing is held, the Commission will publish a separate notice in accordance with 16 CFR 1.12(a) (''initial notice of informal hearing'').

I. Background

The Commission published, on November 8, 2022, an advance notice of proposed rulemaking (''ANPR'') under the authority of Section 18(a)(1)(B) of the FTC Act, 15 U.S.C. 57a(a)(1)(B);[2] which authorizes the Commission to promulgate, modify, or repeal trade regulation rules that define with specificity acts or practices that are unfair or deceptive in or affecting commerce within the meaning of Section 5(a)(1) of the FTC Act, 15 U.S.C. 45(a)(1).

The ANPR described the Commission's history of educating industry and consumers about the use of deceptive reviews and testimonials and of taking law enforcement action against certain unfair or deceptive acts or practices involving consumer reviews or testimonials.[3] Specifically, the ANPR discussed: (a) the use of reviews or endorsements by people who do not exist, who did not actually use or test the product or service, or who were misrepresenting their experience with it; (b) review hijacking, where a seller steals or repurposes reviews of another product; (c) marketers offering compensation or other incentives in exchange for, or conditioned on, the writing of positive or negative consumer reviews; (d) owners, officers, or managers of a company (i) writing reviews or testimonials of their own products or services, or publishing testimonials by their employees or

[1] The Commission elects not to provide a separate, second comment period for rebuttal comments. *See* 16 CFR 1.11(e) (''The Commission may in its discretion provide for a separate rebuttal period following the comment period.'').

[2] Fed. Trade Comm'n, ANPR: Trade Regulation Rule on the Use of Reviews and Endorsements (''ANPR''), 87 FR 67424 (Nov. 8, 2022), *https://www.federalregister.gov/documents/2022/11/08/2022-24139/trade-regulation-rule-on-the-use-of-reviews-and-endorsements.*

[3] The ANPR was entitled ''Trade Regulation Rule Concerning Reviews and Endorsements.'' The Commission has decided to change the name of the proposed rule to ''Trade Regulation Rule on the Use of Consumer Reviews and Testimonials,'' to better reflect its content.

family members, which fail to provide clear and conspicuous disclosures of those relationships, or (ii) soliciting reviews from employees or relatives without instructing them to disclose their relationships; (e) the creation or operation of websites, organizations, or entities that purportedly provide independent reviews or opinions of products or services but are, in fact, created and controlled by the companies offering the products or services; (f) misrepresenting that the consumer reviews displayed represent most or all of the reviews submitted when, in fact, reviews are being suppressed based upon their negativity; (g) the suppression of customer reviews by physical threat or unjustified legal threat; and (h) selling, distributing, or buying followers, subscribers, views, and other indicators of social media influence. The ANPR also asked a series of questions to inform the Commission's determination about whether it has reason to believe that such practices are prevalent and, if so, whether and how to proceed with an NPRM.[4] During the 60-day comment period, the Commission received 42 responsive comments.

Based on the substance of these comments, as well as the Commission's history of enforcement and other information discussed below, the Commission is now exercising its authority under Section 18(a)(1)(B) of the FTC Act to propose a trade regulation rule that defines conduct that, in the context of consumer reviews or testimonials, constitutes unfair or deceptive acts or practices. The Commission has reason to believe that certain unfair or deceptive practices involving consumer reviews or testimonials are prevalent[5] and that proceeding with this rulemaking is in the public interest.

After reviewing the comments and because the Commission believes it would be in the public interest to move forward expeditiously with this rulemaking proceeding, the Commission has decided to issue this NPRM without holding the public workshops originally contemplated in the ANPR. Upon reviewing the ANPR comments, the Commission determined that conducting public workshops at that stage of the proceeding would not provide additional unique viewpoints or issues. Instead, by issuing this NPRM and analyzing the comments submitted in response, the Commission will be able to further develop the record, receive comments on potential alternatives, and decide whether additional events or methods are needed to facilitate public participation in the rulemaking process.

Below, after discussing the comments, setting out the evidence of prevalence, and explaining its considerations in developing the proposed Rule, the Commission poses specific questions for comment and provides the text of the proposed Rule.

II. Summary of Comments to ANPR

The Commission received 42 responsive comments in response to the ANPR.[6] Twenty-nine comments supported the Commission proceeding with a rulemaking. Four comments expressed the view that a rulemaking was unnecessary, premature, or should not apply to the commenter's constituents. One commenter expressed skepticism about the utility of a rulemaking. The remaining commenters did not express a clear view on the merits of proceeding or did not address the question. Fifteen comments came from individual consumers. Seven comments were submitted by trade associations, five by review platform operators and one by an employee of one such operator, three by small businesses and one by a small business employee, three by consumer advocacy organizations, three by entities dedicated to fighting fake reviews, one by a public interest research center, one by a think tank, one by academic researchers, and one by an insurance marketing organization.

The 15 individual consumers expressed significant concerns about fake consumer reviews and testimonials.[7] One consumer comment declared: ''this rule to extend the FTC power over fraudulent and paid for testimonies and reviews is a necessity. I think . . . protection against these types of scams is an integral need to the people of the United States.''[8] Consumer commenters wrote about the difficulty that many consumers have in identifying fake reviews.[9] One consumer who selected an auto repair shop based upon misleading reviews written by the shop's employees or their spouses spoke of having been personally harmed by deceptive reviews.[10] Two consumer comments said that truthful negative reviews are valuable and should not be suppressed.[11] Two additional consumer commenters spoke of the need to punish and deter bad actors.[12]

The four comments from small businesses or a small business employee were from Ubiquitous Advising, LLC, (''Ubiquitous Advising''), Patrick's Pet Care, an anonymous small business that sells products through a particular online marketplace, and Tammy Provencal, who is a small business employee.[13] Ubiquitous Advising supports the rulemaking, and commented that fake reviews cause more damage than anyone can imagine.[14] It also said that review

[4] ANPR, 87 FR at 67427.

[5] *See* 15 U.S.C. 57a(b)(3) (''The Commission shall issue a notice of proposed rulemaking pursuant to paragraph (1)(A) only where it has reason to believe that the unfair or deceptive acts or practices which are the subject of the proposed rulemaking are prevalent.'').

[6] The comments are publicly available on this rulemaking's docket at *https://www.regulations.gov/docket/FTC-2022-0070/comments.*

[7] Anonymous Cmt. on Trade Regulation Rule on the Use of Reviews and Endorsements (''Cmt. on ANPR'') (Nov. 15, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0006* (''Anonymous Consumer A Cmt.''); Mahzer Zaim, Cmt. on ANPR (Nov. 21, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0008* (''Zaim Cmt.''); Jill Monday, Cmt. on ANPR (Dec. 3, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0010* (''Monday Cmt.''); Donald Kelly, Cmt. on ANPR, (Dec. 7, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0012* (''Kelly Cmt.''); Heather Earl, Cmt. on ANPR (Dec. 11, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0013;* Andrea Sliger, Cmt. on ANPR (Dec. 11, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0014;* Merrill Ahrens, Cmt. on ANPR (Dec. 11, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0015;* Diane Dauite, Cmt. on ANPR (Dec. 11, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0016* (''Dauite Cmt.''); Stephanie Smith, Cmt. on ANPR (Dec. 12, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0017* (''Smith Cmt.''); Anonymous, Cmt. on ANPR (Dec. 13, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0018* (''Anonymous Consumer B Cmt.''); Jim Zevely, Cmt. on ANPR (Dec. 17, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0019* (''Zevely Cmt.''); Frank Evelhoch II, Cmt. on ANPR (Dec. 17, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0021* (''Evelhoch Cmt.''); Anonymous, Cmt. on ANPR (Dec. 26, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0022* (''Anonymous Consumer C Cmt.''); Judy Draper, Cmt. on ANPR (Dec. 28, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0023;* Anonymous, Cmt. on ANPR (Dec. 31, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0025* (''Anonymous Consumer D Cmt.'').

[8] Anonymous Consumer A Cmt. at 1.

[9] Kelly Cmt. at 1; Smith Cmt. at 1; Zevely Cmt. at 1; Evelhoch Cmt. at 1; Anonymous Consumer D Cmt. at 1.

[10] Monday Cmt. at 1.

[11] Dauite Cmt. at 1; Anonymous Consumer B Cmt. at 1.

[12] Zaim Cmt. at 2; Anonymous Consumer C Cmt. at 1.

[13] Ubiquitous Advising, LLC, Cmt. on ANPR (Dec. 29, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0024* (''Ubiquitous Advising Cmt.''); Patrick's Pet Care, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0032* (''Patrick's Pet Care Cmt.''); Anonymous, Cmt. on ANPR (Nov. 28, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0009* (''Anonymous Business Cmt.''); Tammy Provencal, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0042* (''Provencal Cmt.'').

[14] Ubiquitous Advising Cmt. at 1–2.

suppression is just as bad, with businesses threatening, bullying, or suing consumers who are trying to warn other consumers, even when there is zero chance of those businesses winning such a lawsuit.[15] Ubiquitous Advising described a company in its local area that is constantly threatening and bullying reviewers.[16] Patrick's Pet Care did not indicate clearly whether it supports the rulemaking but complained about being attacked with negative reviews.[17] It suggested that people should not be able to post anonymous, non-traceable reviews and that platforms should disclose the names of reviewers.[18] The anonymous small business that submitted a comment did not address the proposed rulemaking and asserted that a particular online marketplace was manipulating the placement of negative reviews.[19] The small business employee supports the rulemaking and stated that a competitor is giving incentives for 5-star reviews.[20]

The five review platforms that submitted comments, Yelp, Inc. (''Yelp''), Trustpilot A/S (''Trustpilot''), Google LLC (''Google''), Tripadvisor LLC (''Tripadvisor''), and Amazon.com, Inc. (''Amazon''), wrote of the importance of reviews to consumers and the lengths to which they go to stop and combat fake reviews.[21] These comments conveyed information both about the prevalence and harm caused by fake review practices.

Yelp, which supports civil penalties for ''businesses and individuals who author, arrange for or pay for deceptive reviews,'' [22] said that an overwhelming majority of consumers who read reviews (83 percent) say they trust online reviews about local businesses.[23] In one Yelp survey, 71 percent of respondents said they would no longer visit a business if they learned the business has fake or compensated online reviews.[24] As a first line of defense, Yelp uses automated software systems in order to detect biased reviews and ''flags a significant percentage of reviews—about 19% based on Yelp's most recent . . . figures—as 'not recommended.' '' [25] Yelp said that groups to facilitate the buying, selling, or exchange of fake reviews exist on various online platforms (*e.g.,* Facebook, Instagram, Twitter).[26] In 2021, Yelp made more than 1,000 reports to online platforms warning them of nearly 950 suspicious groups, posts, or individuals found on their sites.[27] Yelp also wrote that ''abusive and questionable or unjustified legal threats are another form of review suppression that Yelp constantly confronts'' and that its 2021 data shows a majority of such threat alerts ''stemmed from beauty and health categories—businesses consumers often turn to when making critical life decisions or that can otherwise be sensitive in nature.'' [28]

Trustpilot, a Danish company operating a website that hosts reviews of businesses worldwide, did not appear to support or oppose the rulemaking. It said that of the 46.7 million Trustpilot reviews written globally in 2021, it removed 2.7 million fake reviews.[29] In 2021, Trustpilot identified and took action against more than 60,000 reviews about United States businesses that were submitted by accounts it deemed to be companies or individuals who offered fake reviews for sale online.[30] It noted that it is appropriate for consumers to review a service provider with which they have had an experience even if they did not make a purchase.[31] In 2021, Trustpilot detected and removed as biased just over 8,000 reviews for United States businesses written by owners, officers, or employees of the company reviewed, or their family members.[32] Trustpilot stated that such behavior does not necessarily reflect intentional fraud.[33] It commented that it is aware of cases outside of Trustpilot in which the suppression of negative reviews has occurred on retailer or business websites.[34] It has seen some cases, mostly outside of the US, in which businesses have threatened reviewers if they do not delete a negative review.[35] In response to the ANPR, Trustpilot said it is possible that, before moving to regulation, there may be benefits in seeking to maximize the effects of other steps, such as educating businesses and consumers or developing codes of conduct.[36] It noted that while regulation could send a strong signal, it may face the challenge of being quite static in a dynamic and fast-paced environment.[37]

Google supports the rulemaking.[38] It said that fake reviews undermine users' confidence in the information available on its platform.[39] Google uses both automated systems and human operators to monitor compliance with its policies and identify and remove fake reviews.[40] Spammers constantly evolve their tactics, so distinguishing between fake and authentic reviews is an ongoing battle.[41] For example, in response to advances in Google's detection and mitigation capabilities, bad actors have adapted, such as by using Virtual Private Networks (''VPNs'') to evade routine detection.[42] Google said that businesses may also have strong incentives to buy positive reviews, which exacerbates the problem.[43] In addition, many reviews displayed on its platform are sourced or surfaced from third parties (*e.g.,* from the merchant website where consumers purchased the product or service), and it can be more difficult to detect when such reviews are fake because Google lacks access to some signals of inauthentic activity, such as the account that created the review being used to post duplicate content.[44] In 2022, Google removed millions of reviews from Google Play that it determined to be fake, inorganic, or otherwise malicious.[45] In 2021, users submitted around one billion Google Maps reviews and Google blocked or removed more than 95 million of them for violating its policies.[46] Google also removed another one million reviews that were reported

[15] *Id.* at 1.

[16] *Id.*

[17] Patrick's Pet Care Cmt. at 1–2.

[18] *Id.* at 2.

[19] Anonymous Business Cmt. at 1–2.

[20] Provencal Cmt. at 1.

[21] Yelp, Inc., Cmt. on ANPR (Jan. 6, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0028* (''Yelp Cmt.''); Trustpilot A/S, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0031* (''Trustpilot Cmt.''); Google LLC, Cmt. on ANPR, (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0034* (''Google Cmt.''); Tripadvisor LLC, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0036* (''Tripadvisor Cmt.''); Amazon.com, Inc., Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0041* (''Amazon Cmt.'').

[22] Yelp Cmt. at 12. At the same time, Yelp said that because ''such deceptive review practices are already illegal under Section 5 of the FTC Act,'' it ''recommends against additional rulemaking that is specifically directed toward liability for deceptive reviews.'' The Commission has difficulty reconciling these two comments as the Commission could not adopt new civil penalties without rulemaking.

[23] *Id.* at 4.

[24] *Id.*

[25] *Id.* at 6.

[26] *Id.* at 8.

[27] *Id.*

[28] *Id.* at 11–12.

[29] Trustpilot Cmt. at 2. Trustpilot noted that it defines ''fake reviews'' more broadly than was used in the FTC's ANPR.

[30] *Id.* at 3.

[31] *Id.* at 3–4.

[32] *Id.* at 7.

[33] *Id.*

[34] *Id.* at 8.

[35] *Id.* at 9.

[36] *Id.* at 16.

[37] *Id.* at 17.

[38] Google Cmt. at 9.

[39] *Id.* at 1, 2, 9.

[40] *Id.* at 1.

[41] *Id.* at 3.

[42] *Id.*

[43] *Id.*

[44] *Id.* at 3, 6.

[45] *Id.* at 8.

[46] *Id.*

directly to it, and it disabled more than one million user accounts due to policy-violating activity.[47] Google urged the Commission to focus on those posting fake reviews rather than on the platforms.[48]

Tripadvisor agrees that deceptive actions by bad actors harm consumers and honest businesses.[49] In 2021, of the 26 million reviews submitted to Tripadvisor, it identified 3.6 percent as violating its fraud guidelines.[50] It said that in certain scenarios it can be difficult to distinguish authentic reviews from fake.[51] Tripadvisor also said that efforts to suppress negative reviews, including by threatening reviewers, is one of the problems that plague the online consumer review ecosystem.[52] Finally, it believes that targeted authority for the FTC to impose financial penalties on bad actors can be an element of a comprehensive effort to improve the consumer information ecosystem, but that any provision that authorizes the assessment of a financial penalty must be appropriately targeted in both design and enforcement at those who knowingly engage in clearly deceptive and fraudulent practices.[53]

Amazon did not state support for or opposition to the rulemaking. Amazon said that in 2021 alone, it invested more than $900 million and employed more than 12,000 people who were dedicated to protecting customers and its store from fraud and other forms of abuse.[54] Amazon stated that it proactively stopped more than 200 million suspected fake reviews in 2020 alone.[55] Amazon also noted that fraudsters approach its customers through their own websites and on social media and solicit them to write misleading reviews in exchange for money, free products, or other incentives.[56] In 2021, Amazon reported more than 16,000 social media groups that were buying or exchanging misleading reviews to the social media sites that hosted them, including Facebook, Twitter, and Instagram, resulting in the removal of groups with more than 11 million members.[57] In July 2022, Amazon sued more than 10,000 such Facebook groups.[58] Amazon encouraged the FTC to increase the use of its existing authority to pursue fake review brokers, collaborate with other regulators to combat bad actors who facilitate review abuse, continue to provide guidance to legitimate businesses, and educate consumers about how to identify and report fake reviews.[59]

An individual Amazon employee working in the Amazon Risk department for the past 10 years submitted a comment.[60] The commenter personally reviewed thousands of seller and buyer accounts for review abuse and said there is no dispute that deceptive reviews are widespread and harmful to customers.[61] The commenter is ''skeptical about whether the regulation will be effective'' because most online platforms and shopping websites do not require customers to register using real identities in order to leave reviews and because Section 230 of the Communications Decency Act (47 U.S.C. 230) immunizes internet service providers, like Google and Facebook, from lawsuits ''based on claims related to content published by third-parties using their service[s].''[62]

The academic researchers who submitted a comment were Rajvardhan Oak and Zubair Shafiq from the University of California Davis, who had examined reviews on online marketplaces.[63] They infiltrated an ''incentivized review service geared towards Amazon.com'' and discovered solicitations for incentivized five-star reviews for 242,000 products.[64] They found more than 250 groups on Facebook in which reviews were brokered, the largest of which had around 550,000 members.[65] Over the six weeks that they tracked products for which incentivized reviews were sought, no reviews were removed from nearly 50 percent of those products.[66] Although Amazon delists products suspected of seeking incentivized reviews, only 25 of the 1,600 products they were tracking were removed by Amazon during the six-week period.[67] They also said that, in response to Amazon's lawsuits against Facebook groups, group administrators and agents simply created alternate communication channels, such as Signal/Telegram groups, and circulated the details of the alternatives.[68]

The Commission received comments from three entities dedicated to fighting fake reviews: the Transparency Company, Fake Review Watch, and Fakespot, Inc.[69] All three commenters asserted that the strategies that are currently being used by review platforms are insufficient.[70]

The Transparency Company, which supports a rulemaking, said that its research suggests that the major review websites are unable to detect a majority of fake reviews online.[71] It estimated that 8.5 percent of published reviews—for all industries—are fake, and provided a link to its fake review research, which asserted that 10.7 percent of Google reviews, 7.1 percent of Yelp reviews, and 5.2 percent of Tripadvisor reviews were fake.[72] The comment noted that 54 percent of consumers say that they would not buy a product if they suspected it to have fake reviews and estimated that consumer injury from fake reviews is approximately $5 billion per year.[73] It documented over 1,000 examples of fake negative reviews causing injury to competition and it estimates that thousands of lawyers are hired each year to send demand letters to and intimidate the authors of negative consumer reviews.[74] The comment identified platform actions that have been effective in reducing consumer harm associated with fake reviews but said that ending online review fraud would require, among other things, the authentication of consumer reviewers.[75]

Fake Review Watch, which supports a rulemaking, said that there is a robust black market for paid for (or traded for) reviews on Google, Yelp, Facebook, Trustpilot, and numerous other review sites and that many of the transactions are conducted on social media.[76] It

[47] *Id.*

[48] *Id.* at 9.

[49] Tripadvisor Cmt. at 7.

[50] *Id.*

[51] *Id.* at 5–6.

[52] *Id.* at 11.

[53] *Id.* at 10.

[54] Amazon Cmt. at 2.

[55] *Id.*

[56] *Id.* at 2.

[57] *Id.*

[58] *Id.* at 3.

[59] *Id.*

[60] Miao Zhao, Cmt. on ANPR (Dec. 19, 2022), *https://www.regulations.gov/comment/FTC-2022-0070-0020* (''Zhao Cmt.'') at 1.

[61] *Id.*

[62] *Id.* at 1–2.

[63] Rajvardhan Oak and Zubair Shafiq, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0030* (''Oak & Shafiq Cmt.'') at 1.

[64] *Id.* at 3–4.

[65] *Id.* at 4.

[66] *Id.* at 7–8.

[67] *Id.* at 8.

[68] *Id.*

[69] The Transparency Company, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0044* (''Transparency Company Cmt.''); Fake Review Watch, Cmt. on ANPR (Jan. 5, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0026* (''Fake Review Watch Cmt.''); Fakespot, Inc., Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0035* (''Fakespot Cmt.'').

[70] Transparency Company Cmt. at 9, 18; Fake Review Watch Cmt. at 2; Fakespot Cmt. at 1–2.

[71] Transparency Company Cmt. at 9.

[72] *Id.;* Uberall, *The State of Online Review Fraud: An Analysis of 4 Million Reviews on Google, Facebook, Yelp and Tripadvisor* at 15, *https://join.momentfeed.com/hubfs/2021%20Fake%20Reviews/FakeReviews_Report.pdf.*

[73] Transparency Company Cmt. at 16, 18.

[74] Transparency Company Cmt. at 16.

[75] *Id.* at 18–20.

[76] Fake Review Watch Cmt. at 1, 9.

stated that fake reviews are commonplace and often difficult to detect without examining review profile histories across multiple businesses.[77] Fake Review Watch has observed over 100 Facebook groups operating as review exchanges, with hundreds or thousands of members each.[78] The comment also asserted that Google: (a) often allows profiles that posted fake reviews to remain active even after it removes those reviews, (b) provides no alerts to consumers about businesses with fake reviews, and (c) makes fake review detection more difficult by allowing profiles to choose not to display all of their reviews and by not displaying the dates of reviews.[79] The comment also complained about reviews by Yelp Elite members,[80] which Fake Review Watch asserted are automatically recommended and not subject to evaluation by Yelp's recommendation software, and about the inadequacy of Yelp's consumer alerts.[81] Fake Review Watch said that regulators should require review sites to tell consumers everything they know about a business's reviews and to post notices reminding consumers that the site cannot guarantee the truthfulness and accuracy of any review.[82]

Fakespot did not state support for or opposition to a rulemaking. In its comment, Fakespot opined that sellers posting fake reviews and fake review farms are among the malicious actors generating fake online content that, in the last five years, has led to a ''dramatic deterioration'' of trust between sellers, platforms, and consumers.[83]

The three consumer advocacy organizations that submitted comments, Truth in Advertising, Inc. (''TINA''), the U.S. Public Interest Research Group (''US PIRG''), and the National Consumers League (''NCL''), all advocated for a rulemaking.[84]

TINA said that fake reviews are an insidious problem, primarily because consumers have come to rely heavily on reviews in making their online purchasing decisions, and it provided numerous citations to publications regarding the importance of reviews to consumer decision making.[85] It stated that incentives to generate early, positive reviews have led to a proliferation of false and fake reviews—a deceptive marketing tactic that will only continue to flourish if not effectively reined in by regulators.[86] TINA said that, given the Supreme Court's *AMG Capital Management* decision, a rule would substantially improve the agency's ability to combat and deter deception and unfairness in this area.[87]

US PIRG cited findings by industry observers that 30 to 40 percent of online reviews are not genuine, and stated that consumers have no way of knowing which reviews are legitimate.[88] It asserted that fake reviews harm both consumers who are trying to make informed buying decisions and honest businesses, and that, when consumers lose confidence in reviews, legitimate positive reviews do not mean as much.[89] It said that the marketplace is poisoned by outright fake reviews, reviews written in exchange for free items, fake negative reviews written about competitors, review suppression, reviews or endorsements written for consideration, and misrepresentations that a website or a certification or a seal is independent.[90]

NCL said that millions of consumers use reviews every day to inform billions of dollars in purchasing decisions involving both online and offline businesses.[91] It cited an estimate that in 2021, fraudulent reviews cost U.S. consumers $28 billion.[92] NCL also cited a different study which said that, by deceiving buyers into purchasing lower quality and potentially unsafe products, fake reviews lead to $0.12 of consumer welfare lost for every $1 spent online.[93] It said that the practices outlined in the ANPR were all unfair and deceptive, that the sellers and service providers that do not use fake reviews are at a competitive disadvantage, that the effects of a fake review may last up to a month after its deletion or detection, and that the threat of fake negative reviews is being used to extort honest businesses.[94] NCL also asked the Commission to require platforms to implement measures to combat the unfair and deceptive uses of reviews, endorsements, and indicators of social media influence, possibly requiring purchase verification before allowing a user to leave a review and the active policing of reviews.[95] Finally, NCL suggested that the FTC explore options for holding platforms accountable for allowing organized review fraud to flourish.[96]

The seven trade associations that submitted comments, the North American Insulation Manufacturers Association (''NAIMA''), the American Dental Association (''ADA''), the Computer & Communications Industry Association (''CCIA''), the Travel Technology Association (''Travel Tech''), the National Automobile Dealers Association (''NADA''), the National Retail Federation (''NRF''), and the Association of National Advertisers (''ANA''),[97] took widely divergent positions on a rulemaking.

NAIMA and ADA both support a rulemaking.[98] With respect to reviews or other endorsements by nonexistent individuals, NAIMA said that it has challenged misleading claims that were ''supported by avatars or entities that there was no chance of making real contact with.'' [99] It also asserted that testimonials by those misrepresenting their experiences with products are plentiful.[100] Finally, NAIMA stated that it regularly challenges statements about

[77] *Id.* at 1.

[78] *Id.*

[79] *Id.* at 3.

[80] According to Yelp, Yelp Elite members are chosen ''based on a number of things, including well-written reviews, high quality photos, a detailed personal profile, and a history of playing well with others.'' *https://www.yelp-support.com/article/What-is-Yelps-Elite-Squad?l=en_US.*

[81] *Id.* at 4–5.

[82] *Id.* at 9.

[83] Fakespot Cmt. at 1.

[84] Truth in Advertising, Inc., Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0029* (''TINA Cmt.'') at 1; U.S. Public Interest Research Group, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0045* (''US PIRG Cmt.'') at 2; National Consumers League, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0039* (''NCL Cmt.'') at 1. Electronic Privacy Information Center (''EPIC''), which is a public interest research center, submitted a comment supporting a rulemaking. Its comment focused mainly on endorsements by police organizations of one product. Electronic Privacy Information Center, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0043.*

[85] TINA Cmt. at 2–3.

[86] *Id.* at 3.

[87] *Id.* at 3.

[88] US PIRG Cmt. at 1.

[89] *Id.*

[90] *Id.* at 1–2.

[91] NCL Cmt. at 1.

[92] *Id.* at 2.

[93] *Id.*

[94] *Id.* at 3–4.

[95] *Id.* at 4.

[96] *Id.*

[97] North American Insulation Manufacturers Association, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0037* (''NAIMA Cmt.''); American Dental Association, Cmt. on ANPR (Jan. 5, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0027* (''ADA Cmt.''); Computer & Communications Industry Association, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0047* (''CCIA Cmt.''); Travel Technology Association, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0046* (''Travel Tech Cmt.''); National Automobile Dealers Association, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0038* (''NADA Cmt.''); National Retail Federation, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0039* (''NRF Cmt.''); Association of National Advertisers, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0040* (''ANA Cmt.'').

[98] NAIMA Cmt. at 1; ADA Cmt. at 1.

[99] NAIMA Cmt. at 2.

[100] *Id.*

its members' products ''that appear on standalone websites which falsely claim to be independent reviewers.'' [101] ADA wants the FTC to allow dentists to disclose patient information in responding to reviews and to require that reviewers identify themselves.[102]

It is unclear whether Travel Tech or CCIA support a rulemaking. Travel Tech commented that the integrity of reviews is essential to maintain the trust and confidence of the customers of Travel Tech members.[103] It stated that the overwhelming majority of reviews are legitimate and that Travel Tech members have systems in place to address the minority of reviews that can be harmful to consumers or travel-related operators and providers.[104] Travel Tech recommended that the Commission utilize its existing authority to combat nefarious paid review-generation sites, referred to as ''click farms.'' [105] CCIA said that any proposed rulemaking should focus on bad actors engaging in fraudulent behavior, not legitimate endorsements that happen to occur through social media.[106]

NADA commented that rulemaking is unnecessary because the Commission did not identify any harmful market conduct for which remedies to protect consumers do not exist under current Federal and state law and because monetary penalty authority alone is not reason enough to issue a rule.[107] Its comment continued that, if the rulemaking proceeds, the Commission should stick to its stated goal of addressing ''certain types of clear Section 5 violations involving reviews and endorsements'' to ''benefit consumers, help level the playing field, and not burden legitimate marketers.'' [108] With respect to any potential rule provision addressing businesses writing, soliciting, or publishing reviews by their employees or family members, NADA asked that the FTC make clear that a violation ''only arises when the business, and not another entity, affirmatively writes, solicits, and publishes reviews that fail to provide clear and conspicuous disclosures of those relationships'' and that the FTC define the term ''relative.'' [109] The comment asserted that businesses may legitimately ''seek to remove reviews or comments that are off topic or include false statements, advertisements, inappropriate language, or confidential or personal identification information'' or to ''remove comments or review functions on their own websites or certain social media posts.'' [110] NADA also posited other practices that they considered legitimate and did not want prohibited under a possible rule: (a) responding on a comment thread to each negative review, offering an explanation, making customers whole, and asking any successfully satisfied customers to respond on the thread with their satisfaction or update their previously negative review; (b) surveying customer satisfaction and prompting only satisfied customers to leave reviews; (c) reaching out to consumers in an effort to change reviews by addressing their issues, sometimes giving customers something of value in satisfaction of their problems; or (d) highlighting five-star reviews from satisfied customers on a dealer's websites.[111] NADA said it understood that some third-party review websites promoted their services to businesses and if a business did not purchase those services, it would have a negative effect on the consumer reviews shown for the business.[112] Finally, NADA said that the FTC should directly engage with review websites, e-commerce sites, and consumer brands through public workshop conferences.[113]

NRF opposed additional regulation of retailers but not of fake review brokers.[114] It believes that the issue of fake and misleading reviews is important but that fake review brokers are much more likely to mislead consumers and create issues for retailers given the potential for brokers to submit fake reviews in volume.[115] NRF said that the fraudulent tactics employed by review brokers can include: (a) using ''bots'' and artificial intelligence tools to generate reviews on behalf of nonexistent consumers; (b) posting identical, or substantially identical, reviews for multiple different products and/or under multiple consumer accounts; (c) flooding social media platforms such as Twitter, Instagram, and Facebook with false review content, whether as standalone posts or as comments or replies to genuine reviews or consumer questions; (d) creating and operating social media groups or standalone websites that purport to offer benefits like refunds or coupons in exchange for specified types of reviews or ratings; and (e) reimbursing consumers for what would otherwise appear to be bona-fide purchases in exchange for positive 5-star reviews and ratings.[116] NRF opposed requiring retailers to restrict consumer reviews to verified purchasers.[117] It also opposed blanket approaches such as ''requiring manual review of every consumer review and the poster's profile'' or approaches that ''risk inadvertent discriminatory or disparate deletion of reviews based on implicit biases towards certain consumer classes.'' [118] NRF said that if a retailer is actually acting in bad faith (whether by itself or by intentionally engaging a fake review broker to act on its behalf), the FTC can take the step of ''filing a complaint and bringing formal enforcement action seeking monetary damages as it has done several times this year alone.'' [119] It accordingly believes that no new enforcement mechanism is necessary for the Commission to ensure retailers comply with existing law, or to hold them accountable for violations.[120]

ANA asserted that a rulemaking is premature, while making clear that ''ANA does not take the position that fake reviews may not produce economic injury.'' [121] It asserted that the ''FTC has not demonstrated evidence of prevalence and has not identified a particular industry that would justify embarking upon rulemaking that would be sufficient, clear, narrowly tailored, easy to enforce, and not burdensome to legitimate marketers.'' [122] ANA appeared to agree that some of the practices challenged in past FTC cases involving the offering of compensation or other incentives in exchange for, or conditioned on, the writing of positive consumer reviews are problematic and deceptive.[123] It sought to distinguish such practices from other practices that, according to ANA, do not obviously cause consumer harm, such as review gating or the ''mere solicitation of positive reviews.'' [124]

The Commission also received a comment from an insurance marketing organization, Family First Life LLC (''Family First Life''), which supported ''a narrowly tailored rule [that] would benefit consumers, help level the playing field, and not burden legitimate

[101] *Id.*
[102] ADA Cmt. at 1.
[103] Travel Tech Cmt. at 1.
[104] *Id.* at 3.
[105] *Id.* at 4.
[106] CCIA Cmt. at 4.
[107] NADA Cmt. at 1–2.
[108] *Id.* at 3.
[109] *Id.*
[110] *Id.*
[111] *Id.* at 3–4.
[112] *Id.* at 4 n.12.
[113] *Id.* at 5.
[114] NRF Cmt. at 1.
[115] *Id.* at 2.
[116] *Id.* at 2–3.
[117] *Id.* at 6.
[118] *Id.*
[119] *Id.*
[120] *Id.* at 7.
[121] ANA Cmt. at 2, 4.
[122] *Id.* at 1–2.
[123] *Id.* at 6.
[124] *Id.* at 7.

marketers.'' [125] It recommended that any regulation ''be tailored to exclude situations where an employee or independent contractor is leaving a review of their experience working with their employer or principal.'' [126] Family First Life pointed out that when someone ''writes a review of her own personal experience working with a company on workplace-review platforms, such as Glassdoor or Indeed,'' concerns about the reviewer's undisclosed relationship to the company are absent because, on such platforms, ''there is an obvious and assumed relationship between the reviewer and the company.'' [127] Family First Life commented that the ''FTC should not write a rule that sweeps in and penalizes any review just because the reviewer was offered an incentive to write it—without otherwise dictating what the review says.'' [128] Family First Life also stated that the ''FTC should include in any proposed regulation it promulgates a safe harbor for truthful reviews that are incentivized but not influenced, controlled, or conditioned by the entity offering the incentive.'' [129] Finally, it asserted that the FTC should not treat platforms' determinations of policy violations as evidence of rule breaking.[130]

The Commission also received a comment from a non-partisan think tank, the Center for Data Innovation (''CDI'').[131] As part of its comment, CDI asserted that regulation is premature because there are no widely accepted best practices for platforms and platforms are still experimenting with solutions.[132] CDI acknowledged that researchers studying deceptive reviews found that fake reviews do have a large presence online and a significant impact on commerce, citing research and reports that included the following findings, among others: (a) ''around five percent of reviews left for a private-label apparel company were posted by individuals who did not purchase products''; (b) ''around 4 percent of online reviews [we]re fake in 2021''; (c) fake reviews impact nearly $152 billion in global e-commerce revenue; (d) Yelp flagged and filtered out around 16 percent of reviews in 2016; and (e) 20 percent of 41,572 reviews on Tripadvisor were suspicious.[133] It noted that an artificial intelligence (''AI'') system is able to write reviews that are nearly indistinguishable from reviews written by people.[134] CDI commented that fake review brokers help facilitate the creation of fake reviews by connecting bad actors with reviewers, often using ''large groups on websites such as Facebook to find reviewers willing to write reviews in exchange for free products or compensation.'' [135] The comment asserted that the review broker dictates the rating and what the review should say and then pays the reviewer only once the review is accepted and posted.[136] CDI proposed that, instead of engaging in a rulemaking, the FTC should establish partnerships with review companies, e-commerce platforms, and social media companies to establish voluntary best practices to detect and prevent fake reviews.[137]

III. Prevalence of the Consumer Review and Testimonial Practices at Issue

A. Fake or False Consumer Reviews or Testimonials

Comments from the platforms support a finding that fake consumer reviews are prevalent. In 2020, Amazon asserted it proactively stopped more than 200 million suspected fake reviews.[138] In 2021, according to the company, Google blocked or removed more than 95 million Google Maps reviews for policy violations; in 2022, it removed millions of fake, inorganic, or otherwise malicious Google Play reviews.[139] Yelp commented that, in 2021, its recommendation software identified about 19 percent of reviews as ''not recommended.'' [140] In 2021, Tripadvisor reportedly flagged 3.6 percent of reviews submitted (or about one million reviews) as fraudulent.[141] Trustpilot stated that in 2021, accounts deemed to be review sellers submitted more than 60,000 reviews of U.S. businesses; it identified and filtered the reviews and blocked the accounts associated with them.[142]

Several comments spoke about the prevalence of consumer review rings on various online platforms (*e.g.,* Facebook, Instagram, Twitter) that facilitate the buying, selling, or exchange of fake reviews. In 2021, Amazon reported more than 16,000 abusive review-related groups to social media sites, leading to the removal of groups with more than 11 million members.[143] In July 2022, Amazon sued administrators of more than 10,000 Facebook groups that attempted to orchestrate fake reviews on Amazon.com in exchange for money or free products.[144] In 2021, Yelp reported almost 950 suspicious groups, posts, or individuals to online platforms.[145] Fake Review Watch has accessed more than 100 Facebook review exchange groups, each with hundreds or thousands of participants.[146]

The comment from the Amazon employee who reviewed thousands of accounts for review abuse said that deceptive reviews are widespread.[147]

Other comments suggest the platforms may be underestimating the extent of the fake review problem. The Transparency Company estimated 8.5 percent of published consumer reviews are fake.[148] The Fake Review Watch comment explained reviews written by Yelp Elite members are not subject to evaluation by Yelp's automatic software and there is a robust market for Yelp Elite Reviews.[149] US PIRG asserted 30 to 40 percent of online reviews are fabricated or otherwise not genuine.[150] The UC Davis researchers found that nearly 50 percent of the products sold on *Amazon.com* by those seeking incentivized reviews did not have any of their reviews removed during the six-week period the researchers tracked them.[151] CDI cited research regarding the prevalence of fake reviews, including findings that ''around five percent of reviews left for a private-label apparel company were posted by individuals who did not purchase products,'' ''around 4 percent of online reviews [we]re fake in 2021,'' and, based on a third-party analysis of 41,572 reviews, around 20 percent of Tripadvisor reviews were suspicious.[152]

Numerous research reports, several of which are cited in the comments, further establish the prevalence of fake reviews. For example, in 2020, the Department of Homeland Security issued a report that focused on counterfeit and pirated goods but also found that ''the ratings systems across platforms have been gamed, and the

[125] Family First Life LLC, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0049* (''Family First Life Cmt.'') at 1–2.

[126] *Id.* at 9.

[127] *Id.* at 9–10.

[128] *Id.* at 12–13.

[129] *Id.* at 14.

[130] *Id.* at 18.

[131] Center for Data Innovation, Cmt. on ANPR (Jan. 9, 2023), *https://www.regulations.gov/comment/FTC-2022-0070-0048* (''CDI Cmt.'').

[132] *Id.* at 5.

[133] *Id.* at 3.

[134] *Id.* at 3–4.

[135] *Id.* at 5.

[136] *Id.*

[137] *Id.* at 5–6.

[138] Amazon Cmt. at 2.

[139] Google Cmt. at 8.

[140] Yelp Cmt. at 6.

[141] Tripadvisor Cmt. at 7.

[142] Trustpilot Cmt. at 3.

[143] Amazon Cmt. at 2.

[144] *Id.* at 3.

[145] Yelp Cmt. at 8.

[146] Fake Review Watch Cmt. at 1.

[147] Zhao Cmt. at 1.

[148] Transparency Company Cmt. at 9.

[149] Fake Review Watch Cmt. at 4.

[150] US PIRG Cmt. at 1.

[151] Oak & Shafiq Cmt. at 7–8.

[152] CDI Cmt. at 3.

proliferation of fake reviews and counterfeit goods on third-party marketplaces now threatens the trust mechanism itself.'' [153] An Uberall report from 2021 estimated 10.7 percent of Google reviews, 7.1 percent of Yelp reviews, and 5.2 percent of Tripadvisor reviews were fake.[154] A 2021 joint report by the University of Baltimore and CHEQ AI Technologies Ltd., a company that provides online security services, described the ''booming market'' for fake reviews and estimated, based on self-reporting from several major platforms, four percent of global reviews are fake.[155] Also in 2021, Fakespot released a report finding that, in 2020, nearly 37.6 percent of reviews on *Walmart.com* were unreliable, with the figure at 27.6 percent for *Amazon.com.*[156] Further, in its most recent annual local consumer review survey, BrightLocal reported 54 percent of consumers were confident they saw fake reviews on *Amazon.com* in 2022, with the figures being 50 percent for Google and 42 percent for Facebook.[157]

Academic research—some of which, again, is cited in the comments—has also repeatedly confirmed the prevalence of fake reviews.[158] Numerous journalists, including from The Washington Post, The Wall Street Journal, CBC News, and CNBC, have also reported on such prevalence, sometimes having undertaken their own investigations.[159] Further, Which?, a consumer advocacy group based in the United Kingdom, has issued several reports documenting fake and manipulated reviews across multiple platforms.[160]

More recently, concerns have been raised that generative artificial intelligence (''AI'') tools can be used to write product reviews.[161] It has been reported that an AI chatbot is being used to create fake reviews.[162] As the reporting notes, the widespread emergence of AI chatbots is likely to make it easier for bad actors to write fake reviews.

The Commission has brought numerous cases involving allegedly fabricated consumer reviews. *See, e.g.,* Complaint at 9–17, *FTC* v. *Roomster Corp.,* No. 1:22–CV–07389 (S.D.N.Y. Aug. 30, 2022) (alleged purchase and sale of fake app store and other reviews for room and roommate finder app and platform); Complaint at 2–4, *Sunday Riley Modern Skincare, LLC,* No. C–4729 (Nov. 6, 2020) (company personnel allegedly created fake accounts to write fake reviews of company's products on third-party retailer's website); *Shop Tutors, Inc.,* 169 F.T.C. 476, 487–89 (2020) (reviews of LendEDU were allegedly fabricated by its employees, other associates, or their friends and published on a third-party website); Complaint at 20, *FTC* v. *Cure Encapsulations, Inc.,* No. 1:19–cv–00982 (E.D.N.Y. Feb. 26, 2019) (Amazon.com reviews of defendants' product were allegedly fabricated by one or more third parties whom defendants had paid to generate reviews); Complaint at 19, *FTC* v. *Genesis Today, Inc.,* 1:15–cv–00062 (W.D. Tex. Jan. 26, 2015) (Amazon.com product reviews allegedly purchased by defendants); Complaint at 5, 8, *FTC* v. *Dunlevy,* No. 1:11–cv–01226–TWT (N.D. Ga. Apr. 4, 2011) (alleged fake consumer comments).

State Attorneys General have also brought cases challenging allegedly fabricated consumer reviews. *See, e.g.,* Complaint at 4, *Washington* v. *Alderwood Surgical Ctr., LLC,* No. 2:22–cv–01835 (W.D. Wash. Dec. 29, 2022) (creating allegedly fake positive reviews on Google, Yelp, and other review sites); Complaint at 17–22, *State* v. *Amazon Home Warranty LLC,* No. CV2021–007632 (Ariz. Sup. Ct. Maricopa Cnty. May 10, 2021) (disseminated or caused the dissemination of allegedly fake favorable consumer reviews on third-party review websites, including on the

[153] *See, e.g.,* Department of Homeland Security, Combating Trafficking in Counterfeit and Pirated Goods (2020), *https://www.dhs.gov/sites/default/files/publications/20_0124_plcy_counterfeit-pirated-goods-report_01.pdf.*

[154] *See* ''Fake Reviews: How Big a Problem Exactly?,'' Oct. 28, 2021, *https://uberall.com/en-us/resources/blog/how-big-a-problem-are-fake-reviews.* Notably, these percentages refer to reviews that were not blocked by these platforms before publication.

[155] *See* University of Baltimore and CHEQ, ''The Economic Cost of Bad Actors on the Internet: Fake Online Reviews 2021,'' *https://f.hubspotusercontent00.net/hubfs/5228455/Research/Fake%20Online%20Reviews%202021.pdf.*

[156] *See* Fakespot, ''2021 Fakespot US Online Shopping, Ratings & Reviews Analysis Report,'' *https://www.fakespot.com/2021holidayreport.*

[157] *See* Sammy Paget, ''Local Consumer Review Survey 2023,'' Feb. 7, 2023, *https://www.brightlocal.com/research/local-consumer-review-survey/.*

[158] *See, e.g.,* Jesper Akesson et al., ''The Impact of Fake Reviews on Demand and Welfare,'' National Bureau of Economic Research Conference, July 20, 2022, *https://conference.nber.org/conf_papers/f166391.pdf;* Sherry He et al., ''The Market for Fake Reviews,'' 2021, *https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3664992;* Devesh Raval, ''Do Bad Businesses Get Good Reviews? Evidence from Online Review Platforms,'' 2020, *https://deveshraval.github.io/reviews.pdf;* Renee DiResta, ''Manipulating Consumption,'' 2018, *https://medium.com/@noupside/manipulating-consumption-42f2e9013d0b;* Ted Lappas et al., ''The Impact of Fake Reviews on Online Visibility: A Vulnerability Assessment of the Hotel Industry,'' 2016, *https://pubsonline.informs.org/doi/abs/10.1287/isre.2016.0674;* Michael Luca and Georgios Zervas, ''Fake It Till You Make It: Reputation, Competition, and Yelp Review Fraud,'' 62(12) Mgmt. Sci. Dec. 3412–27 (2016), *https://dash.harvard.edu/handle/1/22836596.*

[159] *See, e.g.,* Bob Segall, ''Millions of those 5-star online reviews are fake; Here's how to spot them,'' WTHR, Feb. 15, 2022, *https://www.wthr.com/article/news/investigations/13-investigates/many-of-those-5-star-reviews-you-see-online-are-totally-fake-yelp-google-facebook-false-accounts/531-f175843b-1316-494a-a746-5bdfcada43fa;* Nicole Nguyen, ''Fake Reviews and Inflated Ratings Are Still a Problem for Amazon,'' Wall St. J., June 13, 2021, *https://www.wsj.com/articles/fake-reviews-and-inflated-ratings-are-still-a-problem-for-amazon-11623587313;* Laura Sydell, ''Fake patient reviews are making it increasingly hard to seek medical help on Google, Yelp and other directory sites,'' Wash. Post, June 5, 2021, *https://www.washingtonpost.com/business/2021/06/04/fake-medical-reviews-google-zocdoc-trustpilot/;* Matthew Pierce et al., ''Black market in Google reviews means you can't believe everything you read,'' CBC News, May 4, 2021 (finding that sale of reviews is a growing and widespread problem), *https://www.cbc.ca/news/investigates/fake-reviews-on-google-1.6033859;* Natasha Lomas, ''Apple urged to root out rating scams as developer highlights ugly cost of enforcement failure,'' Tech Crunch, Feb. 3, 2021 (finding that selling fake App Store reviews ''is a booming business''), *https://techcrunch.com/2021/02/03/apple-urged-to-root-out-rating-scams-as-developer-highlights-ugly-cost-of-enforcement-failure/;* Katie Tarasov, ''Amazon is filled with fake reviews and it's getting harder to spot them,'' CNBC, Sep. 6, 2020, *https://www.cnbc.com/2020/09/06/amazon-reviews-thousands-are-fake-heres-how-to-spot-them.html;* Greg Sterling, ''Fake reviews problem is much worse than people know,'' Search Engine Land, Apr. 22, 2020, *https://searchengineland.com/fake-reviews-problem-is-much-worse-than-people-know-333331;* Nick Fernandez, ''It's 2020 and the Google Play Store still has a major fake review problem,'' Android Authority, Feb. 23, 2020, *https://www.androidauthority.com/play-store-fake-review-problem-1082191/;* Eric Griffith, ''39 Percent of Online Reviews Are Totally Unreliable,'' PCMag, Nov. 7, 2019, *https://www.pcmag.com/news/39-percent-of-online-reviews-are-totally-unreliable;* Elizabeth Dwoskin and Craig Timberg, ''How merchants use Facebook to flood Amazon with fake reviews,'' Wash. Post, Apr. 23, 2018, *https://www.washingtonpost.com/business/economy/how-merchants-secretly-use-facebook-to-flood-amazon-with-fake-reviews/2018/04/23/5dad1e30-4392-11e8-8569-26fda6b404c7_story.html.*

[160] *See, e.g.,* Hannah Walsh, ''Apple App store and Google Play flooded with fake reviews,'' WHICH?, Mar. 9, 2023, *https://www.which.co.uk/news/article/apple-app-store-and-google-play-flooded-with-fake-reviews-aEA138U8bUw6;* Sara Spary, ''How Facebook fuels Amazon's fake reviews,'' WHICH?, Jan. 13, 2022 (finding Facebook groups with more than 200,000 members facilitating the sale of fake Amazon reviews), *https://www.which.co.uk/news/2022/01/how-facebook-fuels-amazons-fake-reviews/;* Hannah Walsh, ''How a thriving fake review industry is gaming Amazon marketplace,'' WHICH?, Feb. 16, 2021 (finding a ''thriving industry of review manipulation businesses'' targeting the Amazon marketplace and trading on a ''massive scale''), *https://www.which.co.uk/news/2021/02/how-a-thriving-fake-review-industry-is-gaming-amazon-marketplace/.*

[161] *See, e.g.,* Chat GPT, ''Reader Beware: This Gear Review Was Written by an AI Bot,'' GearJunkie, Dec. 7, 2022, *https://gearjunkie.com/news/chat-gpt-ai-gear-review-msr-pocket-rocket.*

[162] *See* Annie Palmer, ''People are using A.I. chatbots to write Amazon reviews,'' CNBC, Apr. 25, 2023, *https://www.cnbc.com/2023/04/25/amazon-reviews-are-being-written-by-ai-chatbots.html.*

BBB's website); Assurance of Voluntary Compliance at 3–5, *State* v. *Unified Holding Grp., LLC,* No. 2020–06785 (C.P. Cumberland Cnty., Pa. Dec. 16, 2020) (alleged fabricated reviews on the BBB website); Complaint at 15, *State* v. *US Air Ducts & Sky Builders, Inc.,* No. 19–2–24757–6–SEA (Wash. Sup. Ct. Kings Cnty., Sept. 20, 2019) (allegedly created fake Google reviews); Complaint at 8–9, *State* v. *Mechs. Heating & Air Conditioning, LLC,* No. 13108809 (Ga. Sup. Ct. Cobb Cnty., Oct. 11, 2013) (alleged fake favorable customer reviews, including on Yelp.com, Kudzu.com, and Google+Local.com). In September 2013, the New York Attorney General's office announced settlements with 19 companies that allegedly either purchased fake reviews or arranged to have fake reviews posted for their clients.[163]

Numerous private lawsuits have involved purportedly fake consumer reviews. *See, e.g., BHRS Grp., LLC* v. *Brio Water Tech., Inc.,* 553 F. Supp. 3d 793, 797 (C.D. Cal. 2021) (defendant allegedly enlisted individuals to purchase products for the purpose of leaving positive Amazon.com reviews of its products and negative Amazon.com reviews of plaintiff's competing products); *Marksman Sec. Corp.* v. *P.G. Sec.,* No. 19–62467–CIV–CAN, 2021 U.S. Dist. LEXIS 196580, at *43 (S.D. Fla. Oct. 12, 2021) (denying plaintiff's motion for default and granting in part its motion for summary judgment in a case in which defendants paid for positive Google reviews from at least three individuals who never lived in a building that a defendant serviced); *Rubinstein* v. *Ourian,* No. 20–21948–CIV–MORE, 2021 U.S. Dist. LEXIS 171799, at *3–4 (S.D. Fla. Sep. 10, 2021) (order granting motions for summary judgment on claims and counterclaims in a case in which defendant allegedly purchased negative reviews of plaintiff plastic surgeon); *RingCentral, Inc.* v. *Nextiva, Inc.,* No. 19–cv–02626–NC, 2021 U.S. Dist. LEXIS 114042, at *7–8 (N.D. Cal. June 17, 2021) (order denying plaintiff's motion for summary judgment, and granting in part defendant's motion for summary judgment in a case in which plaintiff alleged defendant posted fake positive reviews for itself and fake negative reviews of the plaintiff, and defendant made similar allegations about plaintiff); *AlphaCard Sys. LLC* v. *Fery LLC,* Civil Action No. 19–20110 (MAS) (TJB), 2020 U.S. Dist. LEXIS 147059, at *2 (D.N.J. Aug. 14, 2020) (denying defendant's motion to dismiss in a case in which defendant allegedly ''placed'' hundreds of phony Amazon.com customer reviews on defendant's products); *Stonecoat of Tex., LLC* v. *Procal Stone Design, LLC,* Civil Action No. 4:17CV303, 2019 U.S. Dist. LEXIS 153115, at *7–8 (E.D. Tex. July 25, 2019) (denying motions for summary judgment on claims and counterclaims, and denying motion to strike attachments in a case in which plaintiffs allegedly directed employees and/or representatives to submit fake complaints/negative reviews about defendant and post fake positive reviews about plaintiff); *Super Mario Plumbing* v. *Belodedov,* No. 2:17–cv–02545–TLN–AC, 2018 U.S. Dist. LEXIS 24514, at *1–3 (E.D. Cal. Feb. 14, 2018) (denying motion for preliminary injunction in a case in which defendant allegedly posted fake negative reviews about competitor plaintiff); *SA Luxury Expeditions LLC* v. *Latin Am. for Less, LLC,* No. C 14–04085 WHA, 2014 U.S. Dist. LEXIS 159520, at *1–2 (N.D. Cal. Nov. 12, 2014) (motion to dismiss held in abeyance in a case in which defendant allegedly posted fake negative consumer reviews about competitor plaintiff).

The problem of fake reviews is not limited to the United States. Regulators in other countries, including Canada, the United Kingdom, and Germany, as well as international bodies like the Organisation for Economic Co-operation and Development (OECD), have all stated fake reviews are a growing, thriving, or substantial marketplace problem.[164] The extent of fake reviews outside of the United States lends additional support to the conclusion that fake reviews are prevalent, but the Commission is not determining prevalence based upon such facts.

The Commission has also challenged allegedly fictitious consumer testimonials that appear in advertising. *See, e.g.,* Complaint at 15, 17–18, *FTC* v. *Wellco, Inc.,* No. 1:21–cv–02081 (S.D.N.Y. Mar. 10, 2021) (testimonials allegedly copied from competitors' websites); *Shop Tutors, Inc.,* 169 F.T.C. 476, 488–89 (2020) (allegedly fabricated testimonials); Complaint at 14, 19, *FTC* v. *A.S. Resch., LLC (Synovia),* No. 1:19–cv–3423 (D. Colo. Dec. 5, 2019) (allegedly fake testimonials); Complaint at 20–22, 31, *FTC* v. *Global Cmty. Innovations LLC,* No. 5:19–CV–00788 (N.D. Ohio Apr. 10, 2019) (allegedly fake testimonials); Complaint at 12, 18, *FTC* v. *Fat Giraffe Mktg. Grp. LLC,* No. 2:19–cv–00063–CW (D. Utah Jan. 29, 2019) (the people featured in testimonials allegedly were not real customers); *FTC* v. *Cardiff,* No. ED 18–cv–02104–DMG (PLAx), 2020 U.S. Dist. LEXIS 210930, at *15–16 (C.D. Cal. Oct. 9, 2020) (granting in part FTC motion for summary judgment and finding testimonialists in infomercial had not used the product); Complaint at 12–13, 20, *FTC* v. *Mktg. Architects, Inc.,* No. 2:18–cv–00050–NT (D. Me. Feb. 5, 2018) (allegedly fake testimonials); Complaint at 14, 21, *FTC* v. *Health Res. Labs., LLC,* No. 2:17–cv–00467–JDL (D. Me. Nov. 30, 2017) (allegedly fake testimonials); Complaint at 13, 18, 28, *FTC* v. *XXL Impressions LLC,* No. 1:17–cv–00067–NT (D. Me. Feb. 22, 2017) (defendants allegedly did not know whether consumer endorsers of their products who appeared in their ads actually exist); Complaint at 5, 7, 12–13, *FTC* v. *Anthony Dill,* No. 2:16–cv–00023–GZS (D. Me. Jan. 19, 2016) (allegedly fake testimonials); First Amended Complaint at 75, *FTC* v. *Jeremy Johnson,* No. 10–cv–2203–RLH (GWF) (D. Nev. Feb. 25, 2013) (defendants allegedly hired third parties to post fake positive online articles and web pages purportedly by consumers who had successfully used defendants' product to find government grants); *FTC* v. *Grant Connect, LLC,* 827 F. Supp. 2d 1199, 1228 (D. Nev. 2011) (granting summary judgment on FTC's deception count where defendants presented no evidence showing certain testimonials were genuine), *aff'd in part and vacated in part on other grounds,* 763 F.3d 1094 (9th Cir. 2014); *Buckingham Prods., Inc.,* 106 F.T.C. 116 (1985) (testimonials allegedly do not represent actual and genuine testimonials from customers); *Technobrands, Inc.,* 133 F.T.C. 647, 650, 654–55 (2002) (purported consumer endorsers allegedly did not exist); *Plaza*

[163] Press Release, *A.G. Schneiderman Announces Agreement With 19 Companies To Stop Writing Fake Online Reviews And Pay More Than $350,000 In Fines,* Sept. 23, 2013, *https://ag.ny.gov/press-release/2013/ag-schneiderman-announces-agreement-19-companies-stop-writing-fake-online-reviews.*

[164] *See, e.g.,* Competition Bureau Canada, ''Honest Advertising in the Digital Age,'' Jan. 22, 2020, *https://www.canada.ca/en/competition-bureau/news/2020/01/honest-advertising-in-the-digital-age.html;* UK Competition and Markets Authority, ''CMA expects Facebook and eBay to tackle sale of fake reviews,'' June 21, 2019, *https://www.gov.uk/government/news/cma-expects-facebook-and-ebay-to-tackle-sale-of-fake-reviews;* Germany Federal Cartel Office, ''Bundeskartellamt launches sector inquiry into user reviews,'' May 23, 2019, *https://www.bundeskartellamt.de/SharedDocs/Meldung/EN/Pressemitteilungen/2019/23_05_2019_SU_Nutzerbwertungen.html;* OECD, ''Understanding Online Ratings and Reviews'' at 14–15 (2019), *https://www.oecd-ilibrary.org/science-and-technology/understanding-online-consumer-ratings-and-reviews_eb018587-en;* OECD, ''Good Practice Guide on Online Consumer Ratings and Reviews'' at 6 (2019) (noting evidence that some businesses post fake reviews ''on a large scale''), *http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=DSTI/CP(2019)5/FINAL&docLanguage=En.*

Club, Inc., 80 F.T.C. 62 (1972) (testimonialist allegedly was not a member of respondents' physical fitness facilities and unknown to respondents); *New Standard Publ'g. Co., Inc.,* 47 F.T.C. 1350, 1366 (1951) (some of the testimonials and letters recommending encyclopedia allegedly were not genuine).

The use of fake celebrity endorsements is widespread. A 2018 Better Business Bureau in-depth investigative study found many celebrity endorsements are fake.[165] According to one news report, Ellen DeGeneres and Sandra Bullock both sued 100 anonymous defendants who fraudulently used their names in promoting an anti-aging serum and weight-loss products, and dozens of other celebrities' names have been misappropriated in similar fashion.[166]

The FTC has challenged numerous allegedly false claims that specific celebrities endorsed certain products, services, or businesses. *See, e.g.,* Complaint at 22–23, 27–28, 38–39, *FTC* v. *Effen Ads, LLC,* No. 2:19–cv–00945–RJS (D. Utah Nov. 26, 2019); Complaint at 15, 19–20, 30–31, *Global Cmty. Innovations LLC,* No. 5:19–CV–00788 (N.D. Ohio Apr. 10, 2019); Complaint at 5, 18–20, 22–23, 36, *FTC* v. *Tarr, Inc.,* No. 3:17–cv–02024–LAB–KSC (S.D. Cal. Oct. 3, 2017); Complaint at 12–13, *FTC* v. *Tachht, Inc.,* No. 8:16–cv–01397–JDW–AEP (M.D. Fla. June 1, 2016); Complaint at 13–15, 18, *FTC* v. *Sales Slash, LLC,* No. CV15–03107 (C.D. Cal. Apr. 27, 2015); Complaint at 2, 4–5, *Norm Thompson Outfitters, Inc.,* No. C–4495 (Sept. 29, 2014); Complaint at 15–17, *FTC* v. *Central Coast Nutraceuticals, Inc.,* No. 10 C 4931 (N.D. Ill. Aug. 5, 2010); *The Raymond Lee Org., Inc.,* 92 F.T.C. 489 (1978) (use of the names, photographs, and words of public officials, including members of Congress, allegedly misled consumers that the officials recommended or endorsed the business). Most recently, FTC staff published a blog post to warn consumers about scammers using fake Shark Tank celebrity testimonials and endorsements.[167]

Consumer reviews and testimonials that are not entirely fabricated can still misrepresent the experiences of the purported reviewers and testimonialists, and such misrepresentations are prevalent. This conclusion is reflected in NAIMA's comment, which asserted testimonials by those misrepresenting their experiences with products are plentiful.

The Commission has challenged many advertisements that allegedly misrepresented endorsers' experiences. *See, e.g., FTC* v. *Cardiff,* 2020 U.S. Dist. LEXIS 210930, at *15–16, 48 (testimonialists had already lost weight without using the product); Complaint at 14, 18, *FTC* v. *A.S. Resch., LLC (Synovia),* No. 1:19–cv–3423 (testimonialists had allegedly used a prior product formulation that contained substantially different ingredients); Complaint at 22, 25, *NextGen Nutritionals, LLC,* No. 8:17–cv–2807–T–36AEP (M.D. Fla. Jan. 9, 2018) (testimonials in ads allegedly did not represent the actual experiences of customers); Complaint at 22–24, 27, *FTC* v. *Russell T. Dalbey,* No. 1:11–cv–01396–CMA–KLM (D. Colo. May 26, 2011) (testimonials allegedly misrepresented earnings from brokering promissory notes using defendants' system); *FTC* v. *Data Med. Capital, Inc.,* No. SA CV 99–1266 AHS (EEx), 2010 U.S. Dist. LEXIS 3344, *27 (C.D. Cal. Jan. 15, 2010) (testimonial for one defendant recycled as a fictitious testimonial for a different defendant); Complaint at 17, *FTC* v. *Advanced Patch Techs., Inc.,* No. 104–CV–0670 (N.D. Ga. Mar. 10, 2004) (allegedly testimonialists attributed their weight loss to simply wearing the Pound A Patch but were also provided supervised exercise sessions three times per week); *Esrim Ve Sheva Holding Corp.,* 132 F.T.C. 736, 740 (2001) (testimonial from respondent allegedly did not represent his actual findings and experience with the product); *Computer Bus. Servs., Inc.,* 123 F.T.C. 75, 78–79 (1997) (testimonials by purchasers of home-based business ventures allegedly did not reflect their actual experiences); *Twin Star Prods., Inc.,* 113 F.T.C. 847, 853–54 (1990) (endorsement allegedly did not reflect the honest opinions, findings, beliefs, or experience of the endorser); *National Sys. Corp.,* 93 F.T.C. 58, 63–65 (1979) (some testimonials were allegedly untrue); *Federated Sanitary Corp.,* 85 F.T.C. 130, 133 (1975) (alleging testimonials represented to be from salesmen, franchisees, or other distributors of respondents' products were not made by such individuals, and a substantial number of purported testimonialists had never dealt with the respondents); *Natpac, Inc.,* 79 F.T.C. 454, 459 (1971) (testimonial letters were allegedly prepared by respondents and signed before the purported authors had received the products and had time to evaluate them); *P. Lorillard Co.,* 46 F.T.C. 735, 740 (1950) (alleging testimonials did not present or reflect the actual personal experiences, knowledge, or beliefs of the signers; some testimonialists did not smoke Old Gold cigarettes or any cigarettes; many testimonials were prewritten by respondent's representatives; and many were known by the respondent to be false); *R.J. Reynolds Tobacco Co.,* 46 F.T.C. 706, 731–32 (1950) (endorsements communicated that endorsers exclusively smoked Camel cigarettes when they did not smoke cigarettes, did not smoke Camels exclusively, or could not tell the difference between Camels and other cigarettes).

Accordingly, based on the foregoing evidence, the Commission concludes fake consumer reviews and testimonials, as well as reviews and testimonials that otherwise misrepresent the experiences of the reviewers and testimonialists, are prevalent.

B. Consumer Review or Testimonial Reuse or Repurposing

One type of review deception known as ''review hijacking'' or ''review reuse fraud'' appears to primarily or solely affect online marketplaces with third-party sellers, such as Amazon.com. Vendors and third-party sellers on Amazon's platform can make their own modifications to product pages, or request Amazon's assistance to do so, using features referred to as ''product merging'' and ''product variation.'' Products that are substantially similar and that differ only in narrow, specific ways—such as color, size, or quantity—but that do not alter the core essence of the item, such as a shirt that comes in multiple colors and different sizes, may share a variation relationship. Products in a variation relationship share the same product detail page. Each product will appear as an alternative on the product detail page, and, when a shopper selects a different product in the variation relationship, the content of the product detail page, such as the pictured product, may change. The variation relationship enables buyers to compare and choose among product attributes from a single product detail

[165] *See* Better Business Bureau, Subscription Traps and Deceptive Free Trials Scam Millions with Misleading Ads and Fake Celebrity Endorsements (Dec. 12, 2018), *https://www.bbb.org/article/investigations/18929-subscription-traps-and-deceptive-free-trials-scam-millions-with-misleading-ads-and-fake-celebrity-endorsements.*

[166] *See* Randy Hutchinson, Opinion, Endorsements by stars such as Ellen DeGeneres and Sandra Bullock might be fake, The Tennessean, Jan. 8, 2020, *https://www.tennessean.com/story/opinion/2020/01/08/celebrity-endorsement-of-products-could-be/2834860001/.*

[167] *See* Karen Hobbs, Did your favorite Shark Tank celebrity really endorse THAT? Probably not, Fed. Trade Comm'n Consumer Blog (Feb. 17, 2023), *https://consumer.ftc.gov/consumer-alerts/2023/02/did-your-favorite-shark-tank-celebrity-really-endorse-probably-not.*

page, thereby facilitating customer choice and ease of shopping.

Some vendors and sellers abuse these features by repurposing a listing page for a product that has positive reviews (*e.g.,* a shower caddy or a jar of honey) and using it to sell a completely unrelated product (*e.g.,* a phone charger or a neck brace), thus inflating the star rating for the latter—and going unnoticed unless consumers read the individual reviews closely. By repurposing the page, the review hijacker is implicitly misrepresenting the repurposed reviews are for the second product and the product has more ratings and reviews than it does. The review hijacker may also be misrepresenting that the second product has a higher average star rating or that it has earned ''Best Seller'' or ''Amazon's Choice'' badges. These claims are unquestionably deceptive and of no redeeming value to legitimate marketers.

This problem has persisted since at least 2018 and is prevalent as reflected in reporting by Consumer Reports, The Verge, Buzzfeed News, and others.[168] The reporting provides many examples of review hijacking found on Amazon.com across multiple product categories. The author of the Consumer Reports article stated that experts believe it is an ''acute problem'' and some legitimate Amazon.com sellers are overwhelmed with fighting it. The Verge article calls it a ''common tactic'' and quotes a former Amazon employee as saying ''the problem is way bigger than people realize.'' [169]

The Commission recently brought its first case involving this type of review deception, suing a large vendor that boosted its newly launched products on Amazon.com. The vendor allegedly had Amazon establish variation relationships between the newer products and successful, established products that had more ratings and reviews, high average ratings, or ''Amazon's Choice'' or ''#1 Best Seller'' badges. *See* Complaint at 1–6, *The Bountiful Co.,* No. C–4791 (Apr. 10, 2023).

Accordingly, based on the foregoing evidence, the Commission concludes that the unfair or deceptive reuse or repurposing of consumer reviews is prevalent.

C. Buying Positive or Negative Consumer Reviews

It is common for sellers or their agents to give incentives in exchange for reviews with the incentives conditioned on the sentiment of the reviews. In the review markets discussed in the comments and described above, prospective reviewers are offered free merchandise or money in exchange for 5-star reviews. Social media groups for procuring misleading reviews are prevalent. The UC Davis researchers found 242,000 products for which Amazon sellers solicited incentivized five-star Amazon.com reviews.[170] In addition, the comment from the small business employee said that a competitor of the company for which she worked is providing incentives for 5-star reviews.[171] In another academic study, UCLA researchers analyzed these review markets and resulting reviews on Amazon.com and found the market for fake reviews is large and the practice of buying and selling reviews is widespread.[172]

The Commission has brought cases in which a marketer allegedly provided an incentive for a review or endorsement that was required to be positive. *See, e.g.,* Complaint at 14, 19–20, *FTC* v. *A.S. Resch., LLC (Synovia),* No. 1:19–cv–3423 (allegedly offered consumer endorsers free product in exchange for ''especially positive and inspiring'' reviews); Complaint at 5–6, 8, *Urthbox, Inc.,* No. C–4676 (Apr. 3, 2019) (allegedly provided compensation for the posting of positive reviews on the BBB's website and other third-party websites); Complaint at 2–3, *AmeriFreight, Inc.,* No. C–4518 (Feb. 27, 2015) (allegedly past customers were regularly encouraged to submit reviews of respondent's services in order to be eligible for a $100 ''Best Monthly Review Award'' given to ''the review with the most captivating subject line and best content'' and told that they should ''be creative and try to make your review stand out for viewers to read!'').

Such conduct has also been challenged in private actions. *See, e.g., Marksman Sec. Corp.* v. *P.G. Sec.,* 2021 U.S. Dist. LEXIS 196580, at *4 (denying plaintiff's motion for default and granting in part its motion for summary judgment in which it was undisputed that defendants paid for positive Google reviews).

Regulators in Australia, Denmark, and the United Kingdom, as well as the OECD, have issued guidelines or business guidance indicating companies should not provide incentives for giving positive reviews.[173] While it may lend some additional support to the conclusion that the acts or practices are prevalent, the Commission is not concluding that the conduct is prevalent on the basis that other countries have taken actions.

Accordingly, based on the foregoing evidence, the Commission concludes the giving of incentives for reviews conditioned on the sentiment of the reviews is prevalent.

D. Insider Consumer Reviews and Testimonials

It is quite common for a company's owners, officers, managers, executives, employees, agents, or their relatives, to write consumer reviews or testimonials of its products or services.

According to Trustpilot, in 2021, more than 8,000 reviews for U.S. businesses were written by their owners, officers, or employees, or their family members.[174] In addition, an individual commenter complained of having relied upon misleading reviews written by a business's employees or their spouses before selecting an auto repair shop.[175]

The Commission has challenged numerous instances of deceptive

[168] *See, e.g.,* Sara Spary, ''Top-rated Amazon headphones boosted by 'fake reviews' for toys, mugs and umbrellas,'' WHICH?, Apr. 7, 2022, *https://www.which.co.uk/news/2022/04/top-rated-amazon-headphones-boosted-by-fake-reviews-for-toys-mugs-and-umbrellas/;* Timothy B. Lee, ''Amazon still hasn't fixed its problem with bait-and-switch reviews,'' ARS Technica, Dec. 20, 2020, *https://arstechnica.com/tech-policy/2020/12/amazon-still-hasnt-fixed-its-problem-with-bait-and-switch-reviews/;* Jon Keegan, ''Is This Amazon Review Bullshit?,'' The Markup, July 21, 2020, *https://themarkup.org/ask-the-markup/2020/07/21/how-to-spot-fake-amazon-product-reviews;* Josh Dzieza, ''Even Amazon's own products are getting hijacked by imposter sellers,'' The Verge, Aug. 29, 2019, *https://www.theverge.com/2019/8/29/20837359/amazon-basics-fake-sellers-imposters-third-party-marketplace;* Jake Swearingen, ''Hijacked Reviews on Amazon Can Trick Shoppers,'' Consumer Rep., Aug. 26, 2019, *https://www.consumerreports.org/customer-reviews-ratings/hijacked-reviews-on-amazon-can-trick-shoppers/;* Nicole Nguyen, ''Here's Another Kind Of Review Fraud Happening On Amazon,'' Buzzfeed News, May 29, 2018, *https://www.buzzfeednews.com/article/nicolenguyen/amazon-review-reuse-fraud.*

[169] *See* Dzieza, ''Even Amazon's own products are getting hijacked by imposter sellers,'' *supra* note 168.

[170] Oak & Shafiq Cmt. at 3–4.

[171] Provencal Cmt. at 1.

[172] He et al., ''The Market for Fake Reviews,'' *supra* note 158.

[173] Australian Competition & Consumer Commission, *Online product and service reviews, https://www.accc.gov.au/business/advertising-and-promotions/online-product-and-service-reviews;* Danish Consumer Ombudsman, *Guidelines on publication of user reviews* (2015), *https://www.forbrugerombudsmanden.dk/media/49717/guidelines.pdf;* United Kingdom Competition and Markets Authority, *Online reviews and endorsements* (2015), *https://www.gov.uk/government/consultations/online-reviews-and-endorsements;* OECD, *Good Practice Guide on Online Consumer Ratings and Reviews* (2019), *https://www.oecd-ilibrary.org/science-and-technology/good-practice-guide-on-online-consumer-ratings-and-reviews_0f9362cf-en.*

[174] Trustpilot Cmt. at 7.

[175] Monday Cmt. at 1.

reviews allegedly written by company insiders. *See, e.g.,* Complaint at 21, 26–27, *United States* v. *Vision Path, Inc.,* No. 1:22–cv–00176 (D.D.C. Jan. 25, 2022) (allegedly an executive of the company wrote a review on a third-party site and the co–CEO posted a public response thanking the reviewer); Complaint at 2–4, *Sunday Riley Modern Skincare, LLC,* No. C–4729 (Nov. 6, 2020) (company owner and managers allegedly asked company employees to write product reviews on third-party retailer's website); *Creaxion Corp.,* 167 F.T.C. 71, 78–79 (2019) (company allegedly conducted program that reimbursed individuals, including the CEO and other company employees, for purchasing its product and posting online reviews); Complaint at 5–6, 8–9, *Mikey & Momo, Inc.,* No. C–4655 (May 3, 2018) (Amazon.com reviews allegedly written by company officer and her relatives); Complaint at 10, 12, *FTC* v. *Aura Labs, Inc.,* No. 8:16–cv–02147 (C.D. Cal. Dec. 12, 2016) (app store review and website testimonials allegedly written by CEO or relatives of Chairman); Complaint at 25–27, 32–33, *FTC* v. *Universal City Nissan, Inc.,* No. 2:16–cv–07329 (C.D. Cal. Sept. 29, 2016) (customer reviews on third-party websites allegedly written by managers); Complaint at 10, *United States* v. *Spokeo, Inc.,* No. 2:12–cv–05001–MMM–SH (C.D. Cal. June 7, 2012) (allegedly defendant directed its employees to draft and post comments endorsing its products on news and technology websites; and comments were reviewed and edited by managers and then posted using account names provided by defendant); *Reverb Commc'ns, Inc.,* 150 F.T.C. 782, 783–84 (2010) (owner of public relations agency, her managers, and employees allegedly wrote iTunes store reviews for clients' games).

At least one State Attorney General has challenged alleged insider reviews. *See* Complaint at 15, *State* v. *US Air Ducts & Sky Builders, Inc.,* No. 19–2–24757–6–SEA (Wash. Sup. Ct. Kings Cnty., Sept. 20, 2019) (Google reviews allegedly written by employees, relatives of employees, and the business owner).

The Commission has also challenged testimonials allegedly written by insiders in numerous instances. *See, e.g.,* Complaint at 15, 19–20, *FTC* v. *Health Ctr., Inc.,* No. 2:20–cv–00547 (D. Nev. Mar. 19, 2020) (defendants allegedly used testimonials from their employees that purported to be from ordinary consumers); Complaint at 14, 19, *FTC* v. *A.S. Resch., LLC (Synovia),* No. 1:19–cv–3423 (D. Colo. 2019) (ads allegedly included a testimonial by a 50 percent owner and officer); Complaint at 21, 25–26, *FTC* v. *NutriMost LLC,* No. 2:17–cv–00509–NBF (W.D. Pa. Apr. 20, 2017) (testimonials in ads were allegedly from licensees or franchisees, their relatives, or their employees); *Deutsch LA, Inc.,* 159 F.T.C. 1163, 1168–69 (2015) (public relations firm allegedly asked employees to tweet about client's product); Complaint at 19, 21, *FTC* v. *Genesis Today, Inc.,* No. 1:15–cv–00062 (W.D. Tex. Jan. 26, 2015) (allegedly defendants' promotional materials linked to video testimonials by purported users of their weight-loss products that were provided by their employees); Complaint at 17, *FTC* v. *Advanced Patch Techs., Inc.,* No. 104–CV–0670 (N.D. Ga. Mar. 10, 2004) (shopping mall segment of infomercial with testimonials from ''real people'' allegedly included at least one employee of the defendants or their agents); *Brake Guard Prods., Inc.,* 125 F.T.C. 138, 191 (1998) (published testimonial was allegedly from a dealer/distributor of the product); *Gisela Flick,* 116 F.T.C. 1108, 113–14 (1993) (alleged infomercial endorsement by company's Athletic Director); *Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 144–45, 172 (1984) (testimonials were allegedly by business associates or relatives).

Accordingly, based on the foregoing evidence, the Commission concludes the use of consumer reviews and testimonials written by company insiders—that is, consumer reviews and testimonials written by a company's owners, officers, managers, executives, employees, agents, or their relatives—is prevalent.

E. Company-Controlled Review Websites or Entities

Numerous businesses have set up purportedly independent websites, organizations, or entities that review or endorse their own products.

In numerous cases, the Commission has challenged sellers who allegedly misrepresented that the websites they controlled provided independent opinions of products. *See, e.g.,* Complaint at 2, 8–9, *Son Le,* No. C–4619 (May 31, 2020) (respondents allegedly operated purportedly independent websites that reviewed their own trampolines); *FTC* v. *Roca Labs, Inc.,* 345 F. Supp. 3d 1375, 1389–90 (M.D. Fla. 2018) (defendants operated a purportedly independent, objective website that endorsed defendants' products); Complaint at 21–25, 28, *FTC* v. *NourishLife, LLC,* No. 1:15–cv–00093 (N.D. Ill. Jan. 7, 2015) (defendants allegedly operated a purportedly independent, scientific research website that endorsed a supplement sold only by defendants).

The Commission has also challenged sellers who allegedly created purportedly independent organizations or entities that supposedly reviewed or approved their products or services. *See, e.g.,* Complaint at 3–5, *Bollman Hat Co.,* No. C–4643 (Jan. 23, 2018) (respondents allegedly created a U.S.-origin seal misrepresenting that an independent organization endorsed their products as made in the United States); Complaint at 18–20, 26, *NextGen Nutritionals, LLC,* No. 8:17–cv–2807–T–36AEP (M.D. Fla. Jan. 9, 2018) (alleged misrepresentation that sites displaying the Certified Ethical Site Seal were verified by an independent, third-party program); Complaint at 2–4, *Moonlight Slumber, LLC,* No. C–4634 (Sept. 28, 2017) (respondent represented its baby mattresses had been certified by Green Safety Shield and failed to disclose the shield was its own designation); Complaint at 4–6, *Benjamin Moore & Co., Inc.,* No. C–4646 (July 11, 2017) (respondent allegedly used a ''Green Promise'' seal of its own creation to misrepresent that paints had been endorsed or certified by independent third party); Complaint at 2–4, *ICP Constr. Inc.,* No. 4648 (July 11, 2017) (same); Complaint at 2–3, *Ecobaby Organics, Inc.,* No. C–4416 (July 25, 2013) (manufacturer allegedly misrepresented that seal-providing association was an independent, third-party certifier when it created and controlled that association); *Nonprofit Mgmt. LLC,* 151 F.T.C. 144, 148–49 (2011) (respondents allegedly misrepresented their seal program was endorsed by two independent associations when respondents owned and operated them); Complaint at 34, 37, *FTC* v. *A. Glenn Braswell,* No. 2:03–cv–03700–DT–PJW (C.D. Cal. May 27, 2003) (defendants allegedly established the Council on Natural Nutrition and then misrepresented it was an independent organization of experts who had endorsed defendants' products); *Nat'l Media Corp.,* 116 F.T.C. 549, 559–60 (1993) (respondents allegedly claimed the National Association of Advertising Producers was an existing, independent organization that evaluates commercials for their integrity and excellence); *Revco, D.S., Inc.,* 67 F.T.C. 1158, 1163, 1208–18, 1250–51 (1965) (respondents allegedly created and controlled Consumer Protective Institute and gave their products its seal of approval).

Accordingly, based on the foregoing evidence, the Commission concludes the practice of marketers setting up

purportedly independent websites, organizations, or entities to review or endorse their own products is prevalent.

F. Review Suppression

The ANPR addressed two types of review suppression. One type involves a seller's website representing that the consumer reviews displayed represent most or all of the reviews submitted when, in fact, reviews are being suppressed based upon their negativity. Trustpilot commented that it was aware of the suppression of negative reviews on retailer or business websites.[176]

In a recent case, the Commission alleged a retailer suppressed hundreds of thousands of 1-, 2-, and 3-star reviews submitted to its website. *See* Complaint at 1–2, *Fashion Nova, LLC,* No. C–4759 (Mar. 18, 2022). Staff also publicly addressed this issue in a 2020 closing letter to Yotpo, the company that provided review management services to Fashion Nova and numerous other merchants.[177] FTC staff's investigation of Yotpo revealed more than 4,500 Yotpo merchant clients were only automatically publishing 4- or 5-star reviews. Of the 1-star reviews submitted to merchants not automatically publishing 1-star reviews, just 21 percent were published; and of the 2-star reviews submitted to merchants not automatically publishing 2-star reviews, just 31 percent were published. After FTC staff began investigating Yotpo, it implemented clear and prominent guidance to its clients on their need to promptly post reviews, including negative reviews, and began to automatically post negative reviews that have not been promptly reviewed and acted upon by its clients.[178]

Foreign consumer protection entities have brought several actions involving companies that prevented the publication of negative reviews. An online health-care booking service in Australia, which published patient reviews, admitted it did not publish approximately 17,000 reviews and edited another 3,000 reviews either to remove negative aspects or to embellish positive aspects.[179] An Australian court found a home building company held back bad reviews from its review websites to give a more favorable impression of its services.[180] A New Zealand holiday home rental website pleaded guilty and was fined for removing negative comments about rental properties and its maintenance and management of them, and not publishing any reviews that gave a rating below 3.5 stars.[181] The United Kingdom's Competition and Markets Authority secured an undertaking from an online knitwear retailer that did not publish all genuine, relevant, and lawful reviews submitted by its customers.[182] The problem is sufficiently prevalent that an EU Directive prohibits ''publishing only positive reviews and deleting the negative ones.'' [183] These foreign actions lend additional support to the conclusion that the conduct is prevalent, but the Commission is not determining prevalence based upon such actions.

The other type of review suppression addressed in the ANPR is suppression by unjustified legal threat or physical threat. The comments in response to the ANPR support a determination that such review suppression is prevalent. Yelp said it ''constantly confronts'' the use of ''abusive and questionable or unjustified legal threats'' to suppress reviews.[184] Trustpilot has seen cases, mostly outside of the United States, where businesses have threatened consumers if they do not delete negative reviews.[185] A comment from Ubiquitous Advising described a company in its local area that is constantly threatening and bullying reviewers in order to suppress bad reviews.[186] The Transparency Company said every year thousands of lawyers are hired to intimidate the authors of negative reviews.[187]

In a case against Roca Labs, Inc., the Commission successfully challenged as unfair the defendants' threats to enforce—and their actual enforcement of—non-disparagement clauses in form contracts that were intended to suppress customers' negative reviews.[188] A subsequent FTC case against World Patent Marketing challenged alleged review suppression through physical intimidation as unfair.[189] According to the Commission's complaint, the defendants in that matter ''cultivate[d] a threatening atmosphere through emails to would-be complainants.'' [190] For example, they distributed, through an email to all of their then-existing customers, a blog post discussing an incident that purportedly occurred in their offices: A consumer that allegedly wanted to speak with them about an invention idea was stopped, detained, and expelled by their ''intimidating security team, all ex-Israeli Special Ops and trained in Krav Maga, one of the most deadly of the martial arts.'' [191] The post continued: ''The World Patent Marketing Security Team are the kind of guys who are trained to knockout first and ask questions later.''

State Attorneys General have also challenged the alleged use of unjustified legal threats in attempts to have consumers remove negative reviews. *See, e.g.,* Complaint at 12–14, *Maine* v. *Liberty Bell Moving & Storage, Inc.,* 2:2022cv00204 (D. Me. July 8, 2022); Complaint at 4, *Washington* v. *Alderwood Surgical Ctr., LLC.*

A State Attorney General challenged the alleged suppression of negative reviews through intimidation, albeit not physical intimidation, and false accusations. Complaint at 5–7 and Appendices A–C, *State* v. *Mechs. Heating & Air Conditioning, LLC* (alleged publishing or threatening to publish the names, home addresses, telephone numbers, email addresses, and photographs of consumers who wrote negative reviews, together with accusations that the consumers engaged in illegal or unethical activities or otherwise maligning their character).

Accordingly, based on the foregoing evidence, the Commission concludes the types of review suppression discussed above are prevalent.

G. Indicators of Social Media Influence

In order to sell or market themselves or their products or services, some individuals and businesses misrepresent their social media influence by buying fake followers, fake subscribers, fake

[176] Trustpilot Cmt. at 8.

[177] *See https://www.ftc.gov/system/files/documents/closing_letters/nid/202_3039_yotpo_closing_letter.pdf.*

[178] *See id.*

[179] *See* ''HealthEngine to pay $2.9 million for misleading reviews and patient referrals,'' Australian Competition & Consumer Commission, Aug. 20, 2020, *https://www.accc.gov.au/media-release/healthengine-to-pay-29-million-for-misleading-reviews-and-patient-referrals.*

[180] *See* ''Aveling Homes ordered to pay penalties of $380,000 for misleading review websites,'' Australian Competition & Consumer Commission, Nov. 30, 2017, *https://www.accc.gov.au/media-release/aveling-homes-ordered-to-pay-penalties-of-380000-for-misleading-review-websites.*

[181] *See* ''Bachcare fined for removing negative comments in online reviews,'' RNZ, Dec. 20, 2019, *https://www.rnz.co.nz/news/national/405929/bachcare-fined-for-removing-negative-comments-in-online-reviews.*

[182] *See* ''Retailer hosting reviews on its website: improvement of practices,'' Competition and Markets Authority, Aug. 11, 2016, *https://www.gov.uk/cma-cases/retailer-hosting-reviews-on-its-website-improvement-of-practices.*

[183] *See* Directive (EU) 2019/2161 of the European Parliament and of the Council, Nov. 27, 2019, *https://eur-lex.europa.eu/eli/dir/2019/2161/oj.*

[184] Yelp Cmt. at 11.

[185] Trustpilot Cmt. at 9.

[186] Ubiquitous Advising Cmt. at 1.

[187] Transparency Company Cmt. at 16.

[188] *See FTC* v. *Roca Labs, Inc.,* 345 F. Supp. 3d at 1393–96.

[189] *See* Complaint at 8–10, 12, *FTC* v. *World Patent Mktg., Inc.,* No. 1:17–cv–20848–DPG (S.D. Fla. Mar. 6, 2017).

[190] *Id.* at 9.

[191] *Id.*

views, and other similar inauthentic indicators of such influence.

The Commission addressed the alleged sale and use of such fake and inauthentic indicators in complaint against Devumi, LLC.[192] In that matter, the Commission alleged that, by selling and distributing these indicators to users of various social media platforms, the defendants enabled the purchasers to ''exaggerate and misrepresent their social media influence,'' thereby providing the means and instrumentalities for the purchasers to engage in deception.[193] For example, the defendants allegedly sold fake Twitter followers to actors, athletes, musicians, writers, and other individuals who wanted to increase their appeal as influencers and to motivational speakers, law firm partners, investment professionals, experts, and other individuals who wanted to boost their credibility to potential clients for their services.[194]

At least one State Attorney General has brought a case challenging the alleged misuse of fake indicators of social media influence for commercial purposes. In December 2022, the Washington State Attorney General filed suit against a plastic surgery provider accused of buying tens of thousands of fake ''followers'' on Instagram and thousands of fake ''likes'' on Instagram and other social media to create a false appearance of popularity in its advertising to consumers.[195]

Platforms have also sued the sellers of fake indicators of social media influence. In April 2019, Facebook, Inc., and Instagram LLC sued the operators of websites offering fake engagement services.[196] The operators allegedly used a network of computers or ''bots'' and Instagram accounts to provide fake ''likes,'' ''views,'' and ''followers'' to their customers' Instagram accounts.[197]

Both the FTC and an independent organization have analyzed bots, inauthentic social media accounts, and fake followers. In July 2020, the Commission issued a report to Congress, titled ''Social Media Bots and Deceptive Advertising.''[198] The report stated social media companies have reported removing or disabling billions of inauthentic accounts, the online advertising industry has taken steps to curb bot and influencer fraud, and the computing community is designing sophisticated social bot detection methods, but nonetheless, use of social media bots remains a serious issue.[199] A 2023 report by the NATO Strategic Communications Centre of Excellence, which analyzed the market for inauthentic social media accounts and fake followers for several years, found it is as fast and cheap to buy them now as several years ago, and the platforms' ability to detect and remove them is declining overall.[200] Citing TikTok's own reports that it had removed 1.4 billion fake followers in the second quarter of 2022, the researchers stated the total number of fake followers on that platform during that period was likely much higher, given their experiments found only five percent of all purchased fake engagement was identified and removed in a four-week period. Further, in a 2022 study, researchers found that fake views of YouTube videos are widespread, and that the platform does not correct them quickly.[201]

Accordingly, based on the foregoing evidence, the Commission concludes the sale and misuse of fake indicators of social media influence for commercial purposes is prevalent.

IV. Reasons for the Proposed Rule on the Use of Consumer Reviews and Testimonials

The Commission believes the proposed Rule will substantially improve its ability to combat certain specified, clearly unfair or deceptive acts or practices involving consumer reviews or testimonials. Although such practices are already unlawful under Section 5 of the FTC Act, which prohibits unfair or deceptive acts or practices, the proposed Rule may increase deterrence against these practices in the first instance and will allow the Commission to seek civil penalties against the violators and more readily obtain monetary redress for their victims. As discussed below, the proposed Rule would accomplish these goals without significantly burdening honest businesses and provide benefits to consumers and honest competitors.

The Commission's objective in commencing this rulemaking is to deter certain clearly unfair or deceptive acts or practices involving consumer reviews or testimonials, and expand the remedies available to it in instances where such practices are uncovered. A recent U.S. Supreme Court decision,[202] which overturned 40 years of precedent from the U.S. Circuit Courts of Appeal uniformly holding that the Commission could take action under Section 13(b) of the FTC Act, 15 U.S.C. 53(b), to return money unlawfully taken from consumers through unfair or deceptive acts or practices, has made it significantly more difficult for the Commission to return money to injured consumers.[203] Without Section 13(b) as it had historically been understood, the only method the Commission has to return money unlawfully taken from consumers is Section 19 of the FTC Act, 15 U.S.C. 57b, which provides two paths for consumer redress. The longer path, under Section 19(a)(2), requires the Commission to first issue a final cease-and-desist order—including any resulting appeal. Then, to recover money for consumers, the Commission must prove separately in Federal court that the violator engaged in fraudulent or dishonest conduct.[204] The shorter path to monetary relief is under Section 19(a)(1), which allows the Commission to recover redress directly through a Federal court action and is available only when the Commission alleges violation of a rule.[205] None of the Commission's cases challenging deceptive consumer reviews or testimonials has involved other misconduct for which the Commission

[192] *See* Complaint at 5, *FTC* v. *Devumi, LLC,* No. 9:19–cv–81419–RKA (S.D. Fla. Oct. 18, 2019).

[193] *Id.* at 5.

[194] *Id.* at 3–4.

[195] Complaint at 4, *Washington* v. *Alderwood Surgical Ctr., LLC.*

[196] Complaint at 1, 5–9, *Facebook, Inc.* v. *Arend Nollen,* No. 3:19–cv–02262 (N.D. Cal. Apr. 25, 2019).

[197] *Id.* at 8–9.

[198] *See* Social Media Bots and Deceptive Advertising: Federal Trade Commission Report to Congress, *https://www.ftc.gov/system/files/documents/reports/social-media-bots-advertising-ftc-report-congress/socialmediabotsreport.pdf.*

[199] *Id.* at 5.

[200] *See* NATO Strategic Communications Centre of Excellence, ''Social Media Manipulation 2022/2023: Assessing the Ability of Social Media Companies to Combat Platform Manipulation,'' January 2023, *https://stratcomcoe.org/publications/social-media-manipulation-20222023-assessing-the-ability-of-social-media-companies-to-combat-platform-manipulation/272. See also* Johan Lindquist and Esther Weltevrede, ''Negotiating Authenticity in the Market for Fake Followers on Social Media,'' Social Science Research Council, Oct. 5, 2021 (describing ability of manipulation services to evade platform detection), *https://items.ssrc.org/beyond-disinformation/negotiating-authenticity-in-the-market-for-fake-followers-on-social-media/;* Joseph Cox, ''All of My TikTok Followers Are Fake,'' Vice Motherboard, Aug. 13, 2020 (describing the speed and ease of buying fake followers in bulk), *https://www.vice.com/en/article/z3e8na/get-buy-tiktok-followers-likes-views-cheap-easy.*

[201] *See* Maria Castaldo et al., ''Doing data science with platforms crumbs: an investigation into fakes views on YouTube,'' Sep. 28, 2022, *https://doi.org/10.48550/arXiv.2210.01096.*

[202] *See AMG Cap. Mgmt., LLC* v. *FTC,* 141 S. Ct. 1341, 1352 (2021).

[203] *See* ANPR, 87 FR at 67425 & n.1 (discussing *AMG Cap. Mgmt.*).

[204] *See* 15 U.S.C. 57b(a)(2) (''If the Commission satisfies the court that the act or practice to which the cease-and-desist order relates is one which a reasonable man would have known under the circumstances was dishonest or fraudulent, the court may grant relief.'').

[205] *Compare* 15 U.S.C. 57b(a)(1) (rule violations), *with id.* 57b(a)(2) (Section 5 violations).

sought civil penalties under any of the rules it enforces.

In addition, the longer path to redress under Section 19(a)(2) provides relief only to redress consumer injury, which may be difficult to quantify in certain circumstances. By contrast, with a rule violation, the shorter path to redress under Section 19(a)(1) also gives the Commission the ability to obtain civil penalties, which punish the wrongdoer, provide general and specific deterrence, and do not require quantifiable proof of consumer injury.

Outlawing egregious review and testimonial practices by rule expands the Commission's enforcement toolkit and allows it to deliver on its mission by stopping and deterring harmful conduct and, in some cases, making American consumers whole when they have been wronged. Because fake reviews and the other unfair or deceptive review and testimonial practices described here are so prevalent and so harmful, the unlocking of additional remedies through this rulemaking, particularly the ability to seek civil penalties against violators and obtain redress for consumers or others injured by the conduct, will allow the Commission to more effectively police harmful review and testimonial practices that plague consumers and honest businesses.

V. Overview and Scope of Proposed Rule on the Use of Consumer Reviews and Testimonials

A. Key Definitions

Proposed § 465.1 would provide definitions for 12 terms as they appear in proposed 16 CFR part 465, including, among others, definitions for the terms ''consumer reviews,'' ''consumer testimonials,'' and ''celebrity testimonials.''

The term ''consumer review'' is defined in proposed § 465.1(d) as a consumer's evaluation, or a purported consumer's evaluation, of a product, service, or business that is submitted by the consumer, or purported consumer, and that is published to a website or platform dedicated in whole or in part to receiving and displaying such reviews. The definition states that consumer reviews include consumer ratings, regardless of whether they include any text or narrative.

The definition includes ''purported consumers'' so that it covers reviews by authors who do not exist. It does not include all consumer evaluations of products or services, such as a blog post or other social media post evaluating a product; it is limited to those submitted to a website or platform or portion thereof dedicated to such reviews. Such websites and platforms would include, among other things, third-party review platforms and advertiser and retailer websites that collect and display consumer reviews. A consumer review submitted and published to one website that is republished on a second website is still a consumer review as republished. A consumer review is not necessarily advertising.

The term ''consumer testimonial'' is defined in proposed § 465.1(e) as an advertising or promotional message that consumers are likely to believe reflects the opinions, beliefs, or experiences of a consumer who has purchased, used, or otherwise had experience with a product, service, or business.[206] Proposed § 465.1(b) provides a corresponding definition of the term ''celebrity testimonial.'' It defines the term ''celebrity testimonial'' as an advertising or promotional message that consumers are likely to believe reflects the opinions, beliefs, or experiences of a well-known person who purchased, used, or otherwise had experience with a product, service, or business.

B. Fake or False Consumer Reviews, Consumer Testimonials, or Celebrity Testimonials

Proposed § 465.2 would prohibit certain types of deceptive conduct involving ''consumer reviews,'' ''consumer testimonials,'' and ''celebrity testimonials.''

Proposed § 465.2(a) would prohibit a business from writing, creating, or selling a consumer review, consumer testimonial, or celebrity testimonial that: (a) is by someone who does not exist; (b) is by someone who did not use or otherwise have experience with the product, service, or business that is the subject of the review or testimonial; or (c) materially misrepresents the reviewer's or testimonialist's experience with the product, service, or business.

Proposed § 465.2(b) would render it a deceptive act or practice for a business to purchase consumer reviews, or disseminate or cause the dissemination of consumer or celebrity testimonials, about the business or one of its products or services, if the business knew or should have known that the review or testimonial: (a) was by someone who does not exist, (b) is by someone who did not use or otherwise have experience with the product, service, or business, or (c) materially misrepresents the reviewer's or testimonialist's experience with the product, service, or business. In accordance with proposed § 465.1(h), ''purchase a consumer review'' means to provide something of value, such as money, goods, or another review, in exchange for a consumer review.

Proposed § 465.2(c) would make it a deceptive act or practice for a business to procure consumer reviews about the business or one of its products or services for posting on a third-party platform or website, if the business knew or should have known that the review: (a) was by someone who does not exist, (b) is by someone who did not use or otherwise have experience with the product, service, or business, or (c) materially misrepresents the reviewer's experience with the product, service, or business.

Google's comment said a proposed rulemaking should not apply to review platforms.[207] Proposed § 465.2 accounts for this concern. The provision does not apply to businesses, like third-party review platforms, that disseminate consumer reviews that are not of their products, services, or businesses. Neither does it apply to any reviews that a platform simply publishes and that it did not purchase.

NRF opposed requiring the manual review of every consumer review and poster's profile.[208] Proposed § 465.2 accounts for this concern by not imposing any obligation on those publishing consumer reviews to manually review consumer reviews or poster profiles and by not applying to reviews that a platform simply publishes.

Trustpilot asserted any rule should consider a consumer review to be legitimate if the consumer had experience with the business, even if no purchase was made, and NRF's comment opposed requiring retailers to restrict consumer reviews to verified purchasers.[209] In light of these concerns, proposed § 465.2 does not limit legitimate reviews to reviews by purchasers or verified purchasers. It requires only that the reviewer had experience with the product, service, or business.

NRF also recommended any rule provision addressing fake reviews be limited to review brokers and not apply to the parties purchasing the reviews.[210] It said that buyers of fake reviews should not be covered by a rule because the Commission can already bring a

[206] The definition of a consumer testimonial is based upon the definition of an ''endorsement'' in the Commission's Guides Concerning the Use of Endorsements and Testimonials in Advertising. *See* Guides Concerning the Use of Endorsements and Testimonials in Advertising, 16 CFR 255.0(b).

[207] Google Cmt. at 9.

[208] NRF Cmt. at 6.

[209] Trustpilot Cmt. at 3–4; NRF Cmt. at 6.

[210] NRF Cmt. at 1, 7.

''formal enforcement action seeking monetary damages,'' and it was not opposed to Commission action against such purchasers.[211] The Commission believes a rule should indeed apply to those who knowingly purchase fake reviews given that they are no less culpable for deceiving consumers than the brokers. The Commission's ability to seek monetary relief without a rule applies to both brokers and buyers, and it does not obviate the need for a rule because, as discussed above, seeking such relief is much more difficult without a rule.

C. Consumer Review Repurposing

Proposed § 465.3 would prohibit a business from using or repurposing, or causing the use or repurposing of, a consumer review written or created for one product so it appears to have been written or created for a substantially different product. This could consist of combining substantially different products so that they share consumer reviews or changing a product page so it features a different product but retains the reviews of the prior product, or copying reviews of other products from other sites. The term ''substantially different product'' is defined in proposed § 465.1(j), which establishes that the term refers to a product that differs from another product in one or more material attributes other than color, size, count, or flavor. Although differences in flavor are likely to be material to some consumers in some instances, the question can be highly fact specific. For this reason, combining reviews for a product that has multiple flavors would not be a rule violation, though it could still be a deceptive practice under the FTC Act.

D. Buying Positive or Negative Consumer Reviews

Proposed § 465.4 would prohibit a business from offering compensation or other incentives in exchange for, or conditioned on, the writing or creation of consumer reviews expressing a particular sentiment, whether positive or negative, regarding the product, service, or business that is the subject of the review.

ANA's comment asserted any proposed rulemaking should not address ''review gating'' or the ''*mere* solicitation of positive reviews.'' [212] Review gating occurs when a business asks past purchasers to provide feedback on a product and then invites only those who provide positive feedback to post online reviews on one or more websites. Review gating and the mere solicitation of positive reviews are not covered by the proposed Rule. Although the Commission believes review gating can be deceptive,[213] whether any given instance of review-gating is deceptive can be highly fact specific.

Family First Life commented that the FTC should not promulgate a rule ''that sweeps in and penalizes *any* review just because the reviewer was offered an incentive to write it . . . without otherwise dictating what the review says.'' [214] The proposed Rule does not address incentivized reviews except for those required to express a particular sentiment, but the Commission notes that other uses of incentivized reviews can be deceptive and violate the FTC Act.[215] The deceptiveness of undisclosed incentivized reviews is highly fact specific.

E. Insider Consumer Reviews and Consumer Testimonials

Proposed § 465.5 addresses company insider consumer reviews and consumer testimonials in three different ways. Proposed § 465.5(a) applies to insider reviews and testimonials; proposed § 465.5(b) applies to insider testimonials; and proposed § 465.5(c) applies to insider reviews.

Proposed § 465.5(a) would prohibit an officer or manager of a business from writing or creating a consumer review or consumer testimonial about the business or its products or services if the consumer review or consumer testimonial does not have a clear and conspicuous disclosure of the officer's or manager's relationship to the business. Proposed § 465.1(c) defines ''clear and conspicuous'' to mean that a required disclosure is easily noticeable (*i.e.,* difficult to miss) and easily understandable by ordinary consumers, including in all of the ways listed in the definition. This is the same definition the Commission proposed in its Negative Option Rule Notice of Proposed Rulemaking.[216] In accordance with proposed § 465.1(g), ''officers'' are defined to include a business's owners, executives, and managing members.

Proposed § 465.5(b) applies to consumer testimonials in advertisements disseminated by or on behalf of a business. It would prohibit a business from disseminating or causing the dissemination of certain consumer testimonials about the business or its products or services if the consumer testimonial is written by the business's officers, managers, employees, or agents, or any of their relatives without clear and conspicuous disclosures of those relationships. This provision would apply only when the business knew or should have known of the testimonialist's relationship.

Proposed § 465.5(c) applies to solicitations of employee and other insider reviews. It would prohibit under some circumstances an officer's or manager's solicitation of consumer reviews from employees, agents, or relatives that results in reviews that don't clearly and conspicuously disclose the reviewer's relationship. The provision is limited to situations when the person soliciting the review knew or should have known of the prospective reviewer's relationship and: (a) failed to instruct the prospective reviewer to disclose clearly and conspicuously that relationship, (b) knew or should have known the review appeared without such a disclosure and failed to take remedial steps or, (c) encouraged the prospective reviewer not to make such a disclosure.

NADA recommended any proposed rule provision addressing businesses writing, soliciting, or publishing reviews by their employees or family members clarify that a violation ''only arises when the business, and not another entity, affirmatively writes, solicits, and publishes reviews that fail to provide clear and conspicuous disclosures of those relationships.'' [217] Proposed § 465.5(c) would apply to reviews by employees or family members. Proposed § 465.5(c) is limited to solicitation by an officer or manager, and only when the solicitor failed to advise a disclosure, knew or should have known that a review appeared without such a disclosure and failed to take remedial steps, or encouraged the prospective reviewer not to make such a disclosure. The business would not be liable under the proposed provision for an unsolicited review, for a review about which the solicitor reasonably should not have known, or for a reviewer who refuses to make a disclosure. However, proposed § 465.5(c) reflects the Commission's

[211] *Id.* at 6.

[212] ANA Cmt. at 7.

[213] *See* Endorsement Guides, 16 CFR 255.2(e)(11) (review gating ''may be an unfair or deceptive practice if it results in the posted reviews being substantially more positive than if the marketer had not engaged in the practice'') and 16 CFR 255.2(d).

[214] Family First Life Cmt. at 12–13.

[215] *See, e.g.,* Endorsement Guides, 16 CFR 255.5(b)(6)(ii) (any resulting review that fails to clearly and conspicuously disclose the incentives provided to that reviewer is likely deceptive).

[216] *See* Fed. Trade Comm'n, NPRM: Negative Option Rule, 88 FR 24716, 24734 (Apr. 24, 2023), *https://www.govinfo.gov/content/pkg/FR-2023-04-24/pdf/2023-07035.pdf.*

[217] NADA Cmt. at 3.

belief that businesses should be prohibited not only from publishing insider reviews themselves but also from causing their creation (*e.g.,* when an officer or manager of the business solicits employees to post reviews on third-party review websites and fails to instruct the employees to disclose their relationship to the business).

NADA asked the FTC to define the term ''relative.'' [218] The Commission believes that the limitation to situations in which officers or managers know or should know that they are soliciting a relative for an endorsement or testimonial addresses the comment without the need for a definition.

Family First Life commented that when an independent contractor agent writes a review on a workplace-review platform such as Glassdoor, the reviewer's relationship to the company is obvious and assumed.[219] The Commission agrees, in reviews on such platforms, the relationship is readily apparent and, in effect, already disclosed. The Commission does not believe the proposed Rule needs to specifically address this scenario.

F. Company-Controlled Review Websites or Entities

Proposed § 465.6 prohibits a business from representing that a website, organization, or entity is providing its independent reviews or opinions about a category of businesses, products, or services that includes the business or its products or services, when the business controls, owns, or operates that website, organization, or entity.

G. Review Suppression

Proposed § 465.7 addresses two types of review suppression. The first type, addressed in proposed § 465.7(a), would prohibit anyone from using an unjustified legal threat or a physical threat, intimidation, or false accusation to prevent the creation of a consumer review or cause the removal of all or part of a review. In accordance with proposed § 465.1(l), an ''unjustified legal threat'' is defined as a threat to initiate or file a baseless legal action, such as an action for defamation that challenges truthful speech or matters of opinion.

NADA recommended that any proposed rule not prohibit what it characterized as good faith online reputation management practices, such as a business: (a) reaching out to consumers who have posted negative reviews and attempting to improve their reviews by addressing their concerns (including sometimes giving customers something of value in satisfaction of their complaints), or (b) responding on a comment thread to each negative review, offering an explanation, making customers whole, and asking any successfully satisfied customers to update their previously negative review.[220] Neither proposed § 465.7(a) nor any other proposed Rule provision would prohibit such conduct (assuming that reviewers are not required to remove or change their reviews in order to be made whole).

Proposed § 465.7(b) would prohibit a business from misrepresenting that the consumer reviews of one or more of its products or services displayed on its website or platform represent most or all the reviews submitted to the website or platform if reviews are being suppressed based upon their ratings or their negativity. As proposed, the provision makes clear that the non-publication of consumer reviews for certain enumerated reasons is not considered to be review suppression so long as the criteria for withholding reviews are applied to all reviews submitted without regard to the favorability of the review. The listed acceptable reasons for not publishing a review are: (a) that the review contains: (i) trade secrets or privileged or confidential commercial or financial information, (ii) libelous, harassing, abusive, obscene, vulgar, or sexually explicit content, (iii) the personal information or likeness of another person, (iv) content that is discriminatory with respect to race, gender, sexuality, ethnicity, or another protected class, or (v) content that is clearly false or misleading; (b) the seller reasonably believes it is fake; or (c) the review is wholly unrelated to the products or services offered by or available at the website or platform. These criteria are based upon those enumerated in the Consumer Review Fairness Act, 15 U.S.C. 45b(b)(2) and (3). Moreover, consumers would reasonably expect and often prefer that a business exclude reviews meeting these criteria, so the undisclosed exclusion of such reviews solely due to application of those criteria would be unlikely to mislead or be material to consumers.

NADA stated that businesses should be able to ''remove reviews or comments that are off topic or include false statements, advertisements, inappropriate language, or confidential or personal identification information.'' [221] As to reviews that are ''off topic,'' proposed § 465.7(b) would permit not publishing reviews that are ''wholly unrelated to the products or services offered.'' As to reviews that contain ''false statements,'' proposed § 465.7(b) would permit not publishing reviews that are ''clearly false or misleading.'' It is unclear what the comment meant by reviews that include ''advertisements.'' If NADA means that it is acceptable to delete a review that mentions a competitor, that is not an exception provided in proposed § 465.7(b).[222] With regard to reviews that contain ''inappropriate language,'' proposed § 465.7(b) would permit not publishing reviews containing ''harassing, abusive, obscene, vulgar, or sexually explicit content'' or ''content that is discriminatory with respect to race, gender, sexuality, ethnicity, or another protected class.'' As to reviews that contain ''confidential or personal identification information,'' proposed § 465.7(b) would allow a seller to not publish a review that contains ''trade secrets or privileged or confidential commercial or financial information,'' or the ''personal information . . . of another person.'' NADA also said that businesses should be able to ''remove comments or review functions on their own websites or certain social media posts.'' [223] The proposed Rule does not prohibit or address such conduct.

H. Misuse of Fake Indicators of Social Media Influence

Proposed § 465.8 prohibits the misuse of indicators of social media influence. As defined by proposed § 465.1(f), the term ''indicators of social media influence'' refers to any metrics used by the public to make assessments of an individual's or entity's social media influence, such as followers, friends, connections, subscribers, views, plays, likes, reposts, and comments.

Proposed § 465.8(a) prohibits anyone from selling fake indicators of social media influence that can be used by persons or businesses to misrepresent their influence for a commercial purpose. Proposed § 465.8(b) prohibits

[218] *Id.*

[219] Family First Life Cmt. at 9–10.

[220] NADA Cmt. at 3–4.

[221] *Id.* at 3.

[222] *Cf.* FTC Statement of Policy Regarding Comparative Advertising (1979), *https://www.ftc.gov/legal-library/browse/statement-policy-regarding-comparative-advertising* (''Commission policy in the area of comparative advertising encourages the naming of, or reference to competitors, but requires clarity, and, if necessary, disclosure to avoid deception of the consumer.'').

[223] NADA Cmt. at 3. The NADA also posited that highlighting five-star reviews from satisfied customers on a dealer's websites is a legitimate practice that should not be prohibited under a possible rule. *Id.* at 4. The proposed Rule does not address such a practice. The Commission notes, however, that highlighting five-star reviews from satisfied customers on a dealer's websites or in its other advertising could be a deceptive practice depending on the facts.

anyone from procuring fake indicators of social media influence to misrepresent their influence or importance for a commercial purpose.

I. Severability

Proposed § 465.9 is a severability provision. It provides that the provisions of the proposed Rule are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions will continue in effect.

VI. The Rulemaking Process

The Commission can decide to finalize the proposed Rule if the rulemaking record, including the public comments in response to this NPRM, supports such a conclusion. The Commission may, either on its own initiative or in response to a commenter's express request, engage in additional processes, including those described in 16 CFR 1.12 and 1.13. If the Commission on its own initiative decides to conduct an informal hearing, or if a commenter files an express request for such a hearing, then a separate notice will issue under 16 CFR 1.12(a). Any person who would like to participate by providing an oral statement at any informal hearing must make an express request to do so in response to this NPRM. Based on the comment record and existing prohibitions against unfair or deceptive consumer reviews and testimonials under Section 5 of the FTC Act, the Commission does not here identify any disputed issues of material fact necessary to be resolved at an informal hearing. The Commission may still do so later, on its own initiative or in response to a commenter.

VII. Preliminary Regulatory Analysis

Under Section 22 of the FTC Act, the Commission, when it publishes any NPRM for a rule as defined in Section 22(a)(1), must include a ''preliminary regulatory analysis.'' 15 U.S.C. 57b–3(b)(1). The required contents of a preliminary regulatory analysis are (a) ''a concise statement of the need for, and the objectives of, the proposed rule,'' (b) ''a description of any reasonable alternatives to the proposed rule which may accomplish the stated objective,'' and (c) ''a preliminary analysis of the projected benefits and any adverse economic effects and any other effects'' for the proposed rule and each alternative, along with an analysis ''of the effectiveness of the proposed rule and each alternative in meeting the stated objectives of the proposed rule.'' 15 U.S.C. 57b–3(b)(1)(A)–(C). This NPRM already provided the concise statement of the need for, and the objectives of, the proposed Rule in Section IV above. It addresses the other requirements below.

A. Anticipated Costs and Benefits and Reasonable Alternatives

The Commission is proposing a rule to curb certain unfair or deceptive uses of reviews and testimonials. The proposed Rule contains several provisions to promote accuracy in consumer reviews (henceforth ''reviews'') and, thus, will help the vast majority of American consumers who rely on such reviews to make better-informed purchase decisions. The proposed Rule prohibits: the creation, purchasing, procurement, or dissemination of fake or false reviews; repurposing of reviews for substantially different products; and buying of reviews in exchange for, or conditioned on, positive or negative sentiments. It also includes prohibitions on fake or false consumer or celebrity testimonials, insider reviews, misleading company-controlled review websites or entities, certain review suppression practices, and the misuse of indicators of fake social media influence.

The Commission believes that the benefits of proceeding with the rulemaking will significantly outweigh the costs, but it welcomes public comment and data (both qualitative and quantitative) on any benefits and costs to inform a final regulatory analysis.

In the preliminary analysis below, the NPRM describes the anticipated impacts of the proposed Rule. Where possible, it quantifies the benefits and costs. If a benefit or cost is quantified, it indicates the sources of the data relied upon. If an assumption is needed, the text makes clear which quantities are being assumed. The NPRM measures the benefits and costs of the proposed Rule against a baseline in which no rule regarding consumer reviews has been promulgated by the Commission. The Commission solicits comments from the public to improve these estimates before the promulgation of any final rule.

The estimates in this preliminary analysis attempt to include a broad set of economic actors, using data on the number of entities registered as businesses in the United States, data on retail sales, and data on U.S. consumers who shop online. The Commission invites submission of information pertaining to additional economic actors who would be affected by the proposed Rule. Conversely, the Commission solicits information on whether a more limited set of economic actors would yield improved estimates.

Quantifiable benefits stem from consumer welfare improvements and consumer time savings. With the proposed Rule, online reviews will be more accurate overall, leading consumers to purchase higher-quality products or products that are better-matched to their preferences. The proposed Rule will also lead to more trustworthy aggregate review ratings (*e.g.,* star ratings), leading some consumers to spend less time scrutinizing reviews to determine their validity. Quantifiable costs primarily reflect the resources spent by businesses to review the proposed Rule and to take any preemptive or remedial steps to comply with its provisions. Because the proposed Rule is an application of preexisting law under Section 5 of the FTC Act, the Commission expects these compliance costs to be minimal.

A period of 10 years is used in the baseline scenario because FTC rules are subject to review every 10 years. Quantifiable aggregate benefits and costs are summarized as the net present value over this 10-year period in Table 1.1. The discount rate reflects society's preference for receiving benefits earlier rather than later; a higher discount rate is associated with a greater preference for benefits in the present. The present value is obtained by multiplying each year's net benefit by the discount rate raised to the power of the number of years in the future the net benefit accrues.

TABLE 1.1—PRESENT VALUE OF NET BENEFITS, 2023–2033

[In billions]

	Present value: low-end estimate	Present value: high-end estimate
Total Benefits:		
3% Discount Rate	$59.31	$234.28

TABLE 1.1—PRESENT VALUE OF NET BENEFITS, 2023–2033—Continued

[In billions]

	Present value: low-end estimate	Present value: high-end estimate
7% Discount Rate	50.16	200.26
Total One-Time Costs	0.83	0.00
Net Benefits		
3% Discount Rate	58.48	234.28
7% Discount Rate	49.33	200.26

1. Estimated Benefits of the Proposed Rule

This section describes the beneficial impacts of the proposed Rule, provides preliminary quantitative estimates where possible, and describes benefits that are only assessed qualitatively. The quantifiable estimates reflect benefits stemming from the decrease in online review manipulation on third-party platforms or company websites, which covers most of the prohibitions contained in the proposed Rule. This analysis does not calculate benefits from the other aspects of the proposed Rule—prohibitions on fake or false celebrity testimonials; prohibitions on company-controlled entities that purportedly provide independent opinions; prohibitions on unjustified legal threats or physical threats, intimidation, or false accusations in an attempt to suppress negative consumer reviews; and prohibitions on the misuse of indicators of fake social media influence—because of the limited quantitative research in these areas. The Commission invites comment on research concerning these other aspects of the proposed Rule. The quantified benefits are presented by benefit category, rather than stemming from a specific provision in the proposed Rule, because the relevant provisions have the same end goal—that is, to improve the information available to consumers by reducing the level of review manipulation. Therefore, it is difficult to disentangle the benefits stemming from each provision.

Existing academic literature in economics, marketing, computer science, and other fields documents the importance of online reviews: the number of online reviews and aggregate ratings are extremely important for consumer purchase decisions. It is widely documented that the presence of online reviews improves consumer welfare via reductions in both search costs and the level of information asymmetry that exists prior to purchase.[224]

When making purchase decisions, consumers typically have incomplete information on product quality and attributes. Searching for additional information is costly. Consumers incur costs—including time and effort costs—to seek, evaluate, and integrate incoming information. Online platforms where past users share information about their experiences can significantly lower search costs.

Researchers have also demonstrated consumer reviews create value for consumers beyond a reduction in search costs. Consumers are better able to learn of a product's quality and attributes when there is free-flowing, non-manipulated commentary from past consumers. Consumer reviews lead to ''better'' decisions by increasing the level of information available prior to purchase and reducing uncertainty. By the same token, the academic literature also documents that manipulated or fake reviews lead to reductions in consumer welfare by leading consumers to buy low-quality products or otherwise make suboptimal purchase decisions.

A secondary benefit is deterrence of the specified review and testimonial practices. The proposed Rule is essentially the only means for imposing civil penalties in most cases involving such practices. Civil penalties are not generally available under the FTC Act for this conduct, unless parties are already subject to a relevant Commission order or have been served with a copy of a relevant Notice of Penalty Offenses. Also, as noted above, in many cases involving this conduct, calculating redress or other Section 19 relief may be difficult. Without civil penalties, bad actors have little fear of being penalized for using fraud and deception in connection with reviews and endorsements.

To obtain redress without alleging a rule violation, the Commission must successfully conclude an administrative proceeding including any appeal and file a follow-on Federal case under Section 19 to establish that the conduct is ''one which a reasonable man would have known under the circumstances was dishonest or fraudulent.'' [225] Although the Commission is likely to meet this standard in cases involving the conduct covered by the proposed Rule, it would take substantially more time and resources, and would significantly delay any redress to victims, compared to a case under the proposed Rule violation, which does not require multiple proceedings or a special knowledge requirement.[226]

Given the prevalence of unfair or deceptive conduct involving reviews and testimonials, the Commission will have no shortage of bad actors to investigate; it could invest the extra resources freed up by any final rule into more investigations and actions with respect to consumer reviews or testimonials. In sum, the potential consumer-redress benefits of the proposed Rule are significant: the Commission could put a stop to more inarguably unfair or deceptive consumer reviews or testimonials, return money to more victims, and obtain that redress more quickly.

a. Consumer Welfare Benefits From Better-Informed Purchase Decisions

The study containing the most direct estimate of welfare losses from review manipulation finds that the presence of fake reviews leads consumers to lose

[224] *See, e.g.,* Dina Mayzlin, ''Promotional Chat on the Internet,'' 25(2) *Mktg. Sci.,* 155–63 (2006).

[225] 15 U.S.C. 57b(a)(2). Depending on the egregiousness of the misconduct and the harm it is causing, the Commission also may seek preliminary injunctive relief in Federal court. 15 U.S.C. 53(b).

[226] *See, e.g.,* Press Release, Fed. Trade Comm'n, Marketers of Ab Force Weight Loss Device Agree to Pay $7 Million for Consumer Redress (Jan. 14, 2009), *https://www.ftc.gov/news-events/news/press-releases/2009/01/marketers-ab-force-weight-loss-device-agree-pay-7-million-consumer-redress* (describing a 2009 settlement of a follow-on Section 19 action against Telebrands Corp. that was brought after litigation of a 2003 administrative complaint alleging violations of Section 5 concluded—in this case, the Section 19 action settled instead of being litigated to judgment, which would have taken more time).

$0.12 for every dollar spent in an experimental setting.[227] Due to limited quantitative estimates in the literature, the NPRM assumes this measure of welfare loss encompasses the various types of review manipulation covered by the proposed Rule. It also assumes the proposed Rule causes all fake or manipulated reviews to vanish. Thus, consumers will gain an estimated $0.12 for every dollar spent on goods whose online reviews included fake ones.

To estimate consumer welfare benefits from better-informed purchase decisions, the NPRM first estimates the total amount of sales for which consumers consult online reviews. U.S. e-commerce sales totaled $1.034 trillion in 2022.[228] The NPRM assumes all products sold online had some form of user-generated commentary (*e.g.,* on third-party review platforms, on discussion boards, on company websites, or on social media), and that this commentary factors into consumers' purchase decisions for these goods.

Online reviews are also important for commerce not conducted online, including for revenues earned by the hospitality industry and by other services. Sales for businesses classified as ''Food Services and Drinking Places'' by the U.S. Census totaled $843.61 billion in 2021, which includes revenue from restaurants and bars.[229] The NPRM assumes consumers rely on reviews for only a portion of these sales. Some consumers—particularly those living in rural parts of the country and in smaller cities—may have a small set of familiar food and drink establishments available to them, making online reviews less influential to their decision to patronize a particular one. Moreover, prior research has found online reviews do not impact revenues of chain restaurants.[230] Accordingly, the NPRM assumes consumers rely on reviews for 25 percent of the total revenue generated in the food services and drinking places sector (25 percent of $843.61 billion, or $210.90 billion).[231]

Online reviews are also important for sales in other service sectors. In 2021, total revenue was $247.25 billion for the accommodations sector (which includes hotels and vacation rentals), and total revenue was $56.85 billion for personal services (including beauty salons, barber shops, health clubs, and non-veterinary pet care), totaling $304.10 billion for both sectors.[232] About half of hotel revenue is generated by business travelers, who are likely to rely less on online reviews than leisure travelers do.[233] In addition, pre-paid hotel bookings and vacation rentals booked online are already accounted for in the e-commerce sales figure described above. Furthermore, some consumers may be loyal customers of local salons and other personal services, regardless of these businesses' online reputations. Because of these reasons, the NPRM assumes that a subset of accommodation and personal services revenues is affected by consumer reviews. Similar to the calculation for the food and drinking places industry, the NPRM assumes 25 percent of total accommodation and personal care services revenue is impacted by consumer reviews (25 percent of $304.10 billion, or $76.03 billion). The total estimated revenue for services impacted by consumer reviews is $286.93 billion (the sum of $210.90 billion and $76.03 billion). The Commission seeks comments to improve this estimate.

Combining the revenue estimates described above yields $1.321 trillion in estimated sales of goods or services for which consumers incorporate reviews into their decision-making. In this analysis, the NPRM does not incorporate revenues stemming from the physical sale of goods in retail stores where consumers read online reviews before purchasing items in person. The Commission invites commenters to submit information to quantify non-e-commerce retail sales that are impacted by reviews.

Quantitative estimates of the incidence of fake or false reviews vary by source.[234] Nevertheless, at least three prior studies examining the degree of review manipulation as a proportion of businesses or products (rather than as a proportion of *reviews*) contain similar findings: according to these studies, approximately 10 percent of products or businesses have some manipulated consumer reviews.[235] Thus, a basic approximation of total e-commerce sales involving some review manipulation is 10 percent of $1.034 trillion, or $103.4 billion. Similarly, a basic approximation of review-dependent service industry sales involving some review manipulation is 10 percent of $286.93 billion, or $28.69 billion. The Commission seeks submissions of additional research on the prevalence of review manipulation to improve this estimate.

Importantly, online businesses that engage in review manipulation are likely to earn less revenue than other e-commerce companies. For example, prior research has found independent firms and sellers offering lower-quality products are more likely to engage in review manipulation.[236] Therefore, e-commerce sales affected by review manipulation are likely to be lower than the $103.4 billion in sales described above. A more conservative estimate of e-commerce sales involving review manipulation can be obtained by using

[227] *See* Akesson et al., ''The Impact of Fake Reviews on Demand and Welfare,'' *supra* note 158.

[228] *See* U.S. Census Bureau, ''Quarterly E-Commerce Sales Report,'' Feb. 17, 2023, *https://www.census.gov/retail/ecommerce.html.*

[229] U.S. Census Bureau, ''Service Annual Survey,'' Nov. 22, 2022, *https://www.census.gov/programs-surveys/sas.html* (listing total revenue of $843,605,000,000 for NAICS Code 722 in 2021, the most recent year with data).

[230] *See* Michael Luca, ''Reviews, Reputation, and Revenue: The Case of *Yelp.com*.'' Harvard Bus. Sch. Working Paper 12–016 (2016).

[231] 25 percent is likely to be a reasonable estimate based on the difference in revenues for new restaurants and established restaurants. A study conducted by Toast, Inc. found that new restaurants earn approximately $112,000 in average revenue per year (*https://pos.toasttab.com/blog/on-the-line/average-restaurant-revenue*). This is approximately 25 percent of average revenue for restaurants overall ($486,000, according to the website Eat Pallet, *https://eatpallet.com/how-much-do-restaurants-make-in-a-day).*

[232] *See* U.S. Census Bureau, ''Service Annual Survey,'' *supra* note 229 (listing total 2021 revenue of $247,246,000,000 for NAICS Code 721 and listing total 2021 revenue of $56,845,000,000 for NAICS Codes 812111 through 812199 and NAICS Code 81291).

[233] *See* Linchi Kwok, ''Will business travel spending return to the pre-pandemic level soon?'' Hospitality Net, Sept. 22, 2022, *https://www.hospitalitynet.org/opinion/4112075.html.*

[234] These estimates range from the single digits to over 20 percent. *See* Tripadvisor, ''2023 Review Transparency Report,'' *https://www.tripadvisor.com/TransparencyReport2023* (finding that 4.4% of review submissions were fraudulent); Trustpilot, ''Transparency Report 2022,'' *https://cdn.trustpilot.net/trustsite-consumersite/trustpilot-transparency-report-2022.pdf* (stating that its software removed 5.8 percent of reviews due to being fake); Yelp, ''2022 Yelp Trust & Safety Report,'' *https://trust.yelp.com/trust-and-safety-report* (stating that 19 percent of submitted reviews were marked as ''not recommended'' by Yelp's software); Devesh Raval, ''Do Gatekeepers Develop Worse Products? Evidence from Online Review Platforms,'' *Working Paper,* Feb. 27, 2023, *https://deveshraval.github.io/reviews.pdf* (finding that the share of hidden (likely fake) Yelp reviews is as high as 47 percent).

[235] *See* Nan Hu et al., ''Manipulation of online reviews: An analysis of ratings, readability, and sentiments,'' 52(3) *Decision Support Systems* 674–84 (Feb. 2012) (finding that 10.3 percent of books sold on Amazon had manipulated reviews); Luca and Zervas, ''Fake It Till You Make It: Reputation, Competition, and Yelp Review Fraud,'' *supra* note 158 (finding that 10 percent of Boston, MA restaurants had filtered 5-star reviews on Yelp) (Table 3, row 4); Raval, ''Do Gatekeepers Develop Worse Products? Evidence from Online Review Platforms,'' *supra* note 234 (finding that 9.7 percent of businesses with reviews or complaints with the Better Business Bureau are of low quality, where fake reviews inflate ratings) (Table III, column 3, row 1).

[236] *See* He et al., ''The Market for Fake Reviews,'' *supra* note 158; Dina Mayzlin et al., ''Promotional Reviews: An Empirical Investigation of Online Review Manipulation,'' 104(8) The Am. Econ. Rev. 2421–55 (2014).

price differentials of review-manipulated products versus others. Because products with online review manipulation have price points approximately 19 percent of the average price of goods sold online (according to research using data from Amazon),[237] a more conservative estimate of review-manipulated products' revenue is 1.9 percent (19 percent × 10 percent) of all $1.034 trillion in e-commerce sales, or $19.65 billion. Because the Commission does not have data on the revenue or quantities sold of review-manipulated products, the NPRM assumes revenue is constant across price points and rely solely on the price differential to approximate revenue. The NPRM does not similarly adjust revenues for non-e-commerce firms (*e.g.,* restaurant and hotels) because there is less variation in prices in those industries. The Commission invites commenters to submit information to improve this estimate.

The NPRM estimates annual welfare gains by applying the $0.12 estimate, described above, to the estimated amount of U.S. sales likely to have some manipulated consumer reviews, yielding an annual estimate of welfare gains in the range of $5.80 billion (12 percent of $48.34 billion, the sum of $19.65 billion and $28.69 billion) and $15.85 billion (12 percent of $132.09 billion, the sum of $103.4 billion and $28.69 billion). Assuming e-commerce sales increase linearly over the next ten years at the same rate as they did in the past year,[238] the present value of consumer welfare improvements from better-informed purchasing decisions is estimated to be between $50.16 and $199.40 billion as described in Table 2.1.

TABLE 2.1—ESTIMATED BENEFITS FROM CONSUMER WELFARE IMPROVEMENTS FROM PURCHASE DECISIONS

Percent of e-commerce revenue impacted by review manipulation	Total annual welfare improvements from better-informed purchase decisions (in billions)	Total 10-year (2023–2033) welfare improvement, 3% discount rate (in billions)	Total 10-year (2023–2033) welfare improvement, 7% discount rate (in billions)
10	$15.85	$199.40	$170.43
1.9	5.80	59.31	50.16

b. Consumer Time Savings From Increased Reliability of Summary Ratings

The proposed Rule's prohibitions against deceptive and unfair consumer review practices would increase the reliability of consumer reviews. The NPRM assumes this improvement in the dependability of reviews will lead consumers to place more trust in aggregate measures (*e.g.,* aggregate star ratings), which many review settings use to summarize consumer reviews. This in turn will lead some consumers to spend less time scrutinizing individual reviews to detect red flags commonly found in manipulated reviews (*e.g.,* spelling and grammar mistakes, generic highly positive or negative statements, and lack of detail). Therefore, the proposed Rule is likely to result in some amount of time savings for consumers who consult online reviews before making purchases.

Approximately 80 percent of Americans are online shoppers.[239] Of those who shop online, 14 percent shop online more than once a week, 20 percent shop online once a week, 23 percent shop online once every two weeks, 25 percent shop online once a month, and the remainder do so every few months.[240] Different age groups of online shoppers spend various amounts of time reading reviews before making a purchase decision. On average, younger consumers spend more time reading reviews than older consumers.[241] This analysis does not incorporate time spent by consumers researching reviews of restaurants, hotels, and other goods and services that are not purchased online because of the limited amount of information available regarding consumers' total time spent on such activities. The Commission invites commenters to submit information related to the time consumers spend reading reviews for goods and services not purchased online.

According to the Bureau of Labor Statistics, the average hourly wage in 2021 was $28.01.[242] Recent research suggests individuals living in the United States value their non-work time at 82 percent of average hourly earnings.[243] Thus, Americans overall value their non-work time at $22.97 per hour on average. The Commission invites comment on this methodology and seeks submissions of additional data related to quantifying Americans' value of time.

The survey data does not specify whether consumers were surveyed regarding the time spent reading reviews before the purchase of a single product or whether the question concerned the purchase of multiple products. This analysis assumes the time listed in the survey results pertains to the purchase of a single product. It also assumes the implementation of the

[237] *See* Davide Proserpio et al., ''How Fake Customer Reviews Do—and Don't—Work,'' Harvard Bus. Rev., Nov. 24, 2020, *https://hbr.org/2020/11/how-fake-customer-reviews-do-and-dont-work.* The authors find that products sold on Amazon with manipulated reviews are typically in the $15 to $40 price range. The midpoint of this range ($27.50) represents 19 percent of the average product's price ($142.74, according to a study conducted by Semrush Inc., *https://www.semrush.com/blog/amazon-pricing-study*).

[238] E-commerce sales increased by 7.7 percent from 2021 to 2022. *See* U.S. Census Bureau, ''Quarterly E-Commerce Sales Report,'' *supra* note 228. Using growth in the past year to predict future e-commerce sales results in a more conservative estimate than using a longer time frame. E-commerce sales experienced higher annual growth rates prior to 2021 (14 percent from 2018 to 2019, 43 percent from 2019 to 2020, and 14 percent from 2020 to 2021). The NPRM does not project revenues for non-e-commerce industries because the two most recent years of data are from 2021 and 2020; linear trends during these years are unique to the pandemic and are unlikely to be accurate for future years.

[239] *See* Pew Research Center, ''Online Shopping and E-Commerce,'' Dec. 19, 2016, *https://www.pewresearch.org/internet/2016/12/19/online-shopping-and-e-commerce.*

[240] *See* Int'l Post Corp., ''Cross-Border E-Commerce Shopper Survey 2022,'' Jan. 2023, *https://www.ipc.be/-/media/documents/public/publications/ipc-shoppers-survey/onlineshoppersurvey2022.pdf.*

[241] *See* BrightLocal, ''Local Consumer Review Survey 2019,'' Dec. 11, 2019, *https://www.brightlocal.com/research/local-consumer-review-survey-2019.*

[242] Bureau of Labor Statistics, ''May 2021 National Occupational and Wage Estimates, Unites States,'' *https://www.bls.gov/oes/current/oes_nat.htm* (listing mean hourly wage of $28.01 for all occupations).

[243] *See* Daniel S. Hamermesh, ''What's to Know About Time Use?,'' 30 J. of Econ. Survs. 198–203 (2016), *https://doi.org/10.1111/joes.12107.*

proposed Rule would reduce the time spent reading reviews by 10 percent. Combining the above figures results in $2.49 billion in consumer time savings per year, or a present value of $18.55 billion to $21.69 billion over a 10-year period, as described in Table 2.2. The Commission invites commenters to submit information to improve this estimate.

In addition, there are likely to be other utility-related benefits consumers receive when reading nonmanipulated online reviews or consulting more accurate aggregate summary measures, such as increased satisfaction (apart from purchasing decisions) and decreased frustration. The Commission is not able to quantify these benefits and invites commenters to submit information to assist with calculating these additional benefits.

Finally, some consumers may spend *more* time reading reviews if reviews are less likely to be fake or otherwise manipulated. This increase in time spent reading reviews may offset any time savings from the increased reliability of summary ratings. Therefore, the NPRM presents another scenario in Table 2.2 where consumers do not gain any benefits from time savings. However, as before, there are likely to be additional benefits difficult to quantify (*e.g.,* decreased frustration) that result from reading more accurate reviews, likely yielding positive net benefits related to reading reviews even when consumers spend more time doing so. The Commission invites comment on methods that would allow us to quantify such benefits.

TABLE 2.2—ESTIMATED BENEFITS FROM TIME SAVINGS

Scenario 1—Improved Reliability of Aggregate Measures Reduces Overall Time Spent Reading Reviews:	
Number of online shoppers, age 18–34 [a]	60,467,204
Average amount of time spent reading online reviews before making a purchase decision (in hours), age 18–34	0.336
Number of online shoppers, age 35–54 [a]	67,273,832
Average amount of time spent reading online reviews before making a purchase decision (in hours), age 35–54	0.231
Number of online shoppers, age 55+ [a]	78,920,814
Average amount of time spent reading online reviews before making a purchase decision (in hours), age 55+	0.167
Total amount of time all online shoppers spend reading online reviews before making a purchase decision (in hours)	48,991,116
Total amount of time U.S. online shoppers spend reading online reviews per year (in hours) [b]	1,728,406,578
Value of time for online shoppers (per hour)	$22.97
Percentage of time saved	10%
Total annual time savings	$3,970,149,909
Total 10-year (2023–2033) time savings, 3% discount rate (in billions)	$34.88
Total 10-year (2023–2033) time savings, 7% discount rate (in billions)	$29.84
Scenario 2—Increase in Time Spent Reading Reviews Offsets Time Savings from Improved Reliability of Summary Measures:	
No quantifiable benefit	$0

[a] 80% of age-specific total U.S. population (Source: Pew Research Center, U.S. Census).
[b] Adjusting for online shopping frequency (Source: International Post Corporation).

c. Benefits Related to Competition

Accurate online reviews have been shown to improve competition. Several studies have found online reviews are particularly important for independent and newer firms.[244] Ratings are more influential for these firms because consumers do not have strong prior beliefs as to their quality. New entrants whose sales benefit from online reviews typically offer higher quality goods and services. On the other hand, lower-quality firms often experience revenue losses with more online review activity.[245]

Relatedly, fake online reviews allow companies to surpass competitors. One study found it only takes 50 fake reviews for a seller to pass any of its competitors in terms of visibility (*e.g.,* via rankings or search results).[246] It follows that by curbing the number of fake or manipulated reviews, the proposed Rule would benefit consumers by improving the competitive environment for legitimate firms selling higher-quality products (*i.e.,* those who do not rely on review manipulation to sell their goods). The benefits resulting from improvements in the competitive environment are difficult to quantify. The Commission invites comment on the best approach to quantifying such benefits.

2. Estimated Costs of the Proposed Rule

This section describes the costs associated with the proposed Rule, provides preliminary quantitative estimates where possible, and describes costs that are only assessed qualitatively.

a. Compliance Costs

The acts and practices prohibited by the proposed Rule are unfair or deceptive under Section 5 of the FTC Act. The proposed Rule targets acts or practices that are clear violations of Section 5, and businesses that are compliant will continue to be compliant. Moreover, the FTC routinely provides guidance to businesses on complying with FTC law, which will make the implications of the proposed Rule easy to understand for a wide range of businesses. Accordingly, the NPRM presents one scenario in Table 3.1 where businesses spend a *de minimis* amount of time interpreting the proposed Rule and make no changes to their current policies.

[244] *See* Luca, ''Reviews, Reputation, and Revenue: The Case of *Yelp.com*,'' *supra* note 230 (finding that chain restaurants have declined in market share as Yelp penetration has increased); Gregory Lewis and Georgios Zervas, ''The Welfare Impact of Consumer Reviews: A Case Study of the Hotel Industry,'' Working Paper, *https://economics.sas.upenn.edu/sites/default/files/filevault/u475/tawelfare.pdf* (finding that demand for independent hotels is more sensitive to reviews on Tripadvisor); Brett Hollenbeck, ''Online Reputation Mechanisms and the Decreasing Value of Chain Affiliation,'' 55(5) J. of Mktg. Resch. 636–54 (2018), *https://www.jstor.org/stable/26966532* (finding that branded, chain-affiliated hotels' premiums over independent hotels have declined substantially largely due to online reputation mechanisms).

[245] *See* Limin Fang, ''The Effects of Online Review Platforms on Restaurant Revenue, Consumer Learning, and Welfare,'' 68(11) Mgmt. Sci. 7793–8514 (2022).

[246] *See* Lappas et al., ''The Impact of Fake Reviews on Online Visibility: A Vulnerability Assessment of the Hotel Industry,'' *supra* note 158.

However, because of the enhanced penalty associated with violating the proposed Rule (relative to *de novo* violations of Section 5 of the FTC Act), businesses may choose to incur additional administrative burdens to ensure compliance. The NPRM presents another scenario in Table 3.1 where businesses notify their employees of the proposed Rule, conduct a review of their processes, and take any steps they deem important to ensure compliance. For firms that already comply with Section 5, these steps might be out of caution so as not to risk the possibility of violating the proposed Rule. For example, some sellers may currently flag and remove reviews on their websites that they reasonably believe are fake. While this practice would not amount to not a violation of the relevant rule provision (proposed § 465.7(b)), promulgation of the proposed Rule may lead some businesses to choose to take extra steps to verify the inauthenticity of such reviews before suppressing them. A business may also decide to notify its employees of the proposed Rule. For example, if certain employees are responsible for posting new product pages or managing the company's social media presence, business owners may wish to notify these employees to ensure compliance. Although cautious firms may elect to conduct additional compliance review, the proposed Rule would not require any additional recordkeeping or notices beyond what is required by Section 5 of the FTC Act.

For the heightened compliance review scenario in Table 3.1, the NPRM makes assumptions about the number of businesses impacted and the number of person-hours involved in compliance activities. In 2019, there were approximately 33.20 million total firms in the United States. 20,868 of these were entities with 500 or more employees (''large companies''), and the remaining 33.19 million had fewer than 500 employees (''small companies'').[247] The NPRM assumes all 20,868 large companies had some form of online consumer review presence (*e.g.,* on third-party business platforms such as Yelp or Google Reviews, or on their own websites). It assumes 74 percent of the 33.19 million small companies (24.56 million companies) had an online consumer review presence.[248]

With heightened compliance review, the NPRM assumes lawyers at large companies, whose time is valued at $61.54 per hour,[249] will spend eight hours conducting a one-time review of the proposed Rule and notifying employees whose role involves creating new product pages, managing the company's social media presence, and any other relevant practices covered by the proposed Rule. It assumes small company owners, whose time is valued at $33.23,[250] spend one hour doing the same.

In addition, some companies may spend time reviewing their automated processes to ensure they comply with the proposed Rule. For instance, they may check any review filtering processes to ensure reviews that are flagged and removed meet the permissible exceptions listed in proposed § 465.7(b). These costs, which companies might incur just once or on a recurring basis, are likely to be minimal. The NPRM does not quantify these process-related costs because, among other things, the Commission does not know the number of firms that might undertake such a review. The Commission invites commenters to submit information to assist with the calculation of these costs.

The total estimated costs are tabulated in Table 3.1. The Commission seeks comments on the assumptions incorporated in these estimates.

TABLE 3.1—ESTIMATED COMPLIANCE COSTS

	2023 Only
Scenario 1—No Review:	
No cost	$0
Total cost	$0
Scenario 2—Heightened Compliance Review:	
Number of large companies (in thousands)	20.86
Cost per hour of rule review and related activities	$61.54
Number of hours of rule review and related activities	8
Subtotal (in millions)	$10.27
Number of small companies with online reviews (in thousands)	24,557.31
Cost per hour of rule review and related activities	$33.23
Number of hours of rule review and related activities	1
Subtotal (in millions)	$816.04
Total cost (in millions)	$826.31

b. Other Impacts of the Proposed Rule

There are several other potential effects from the proposed Rule. While the proposed requirements are far from onerous, there is the possibility some sellers may ''overcorrect'' in response to the higher penalties imposed by the rule compared to existing law. For example, a firm may encounter an excess of fake, negative reviews from a competitor. While proposed § 465.7(b) permits the suppression of reviews the seller reasonably believes are fake, an overcautious seller seeking to suppress fake reviews from competitors may choose to display no reviews whatsoever so as not to risk violating the proposed Rule. Alternatively, such a

[247] *See* U.S. Census Bureau, ''2019 SUSB Annual Data Tables by Establishment Industry,'' *https://www.census.gov/data/tables/2019/econ/susb/2019-susb-annual.html* (listing 6.10 million total firms with at least one paid employee) and ''Nonemployer Statistics,'' *https://www.census.gov/programs-surveys/nonemployer-statistics.html* (listing 27.10 million firms with no paid employees).

[248] 74 percent of small businesses have at least one Google review. *See* BrightLocal, ''Google Reviews Study,'' *https://www.brightlocal.com/research/google-reviews-study/.*

[249] *See* Bureau of Labor Statistics, Occupational Outlook Handbook: Lawyers, *https://www.bls.gov/ooh/legal/lawyers.htm.*

[250] *See* Payscale, ''Average Small Business Owner Salary,'' *https://www.payscale.com/research/US/Job=Small_Business_Owner/Salary.*

firm may take no action towards suspected fake reviews to avoid a possible rule violation. Both of these hypothetical scenarios would likely hurt the information environment for consumers. The Commission believes such unintended consequences of the proposed Rule are very unlikely. The Commission seeks comment on the likelihood of such effects and information on how to best quantify them.

3. Potentially Reasonable Alternatives

One alternative to the proposed Rule is to terminate the rulemaking and rely instead on the existing tools the Commission currently possesses to combat the specified review and testimonial practices, such as consumer education and enforcement actions brought under Sections 5 and 19 of the FTC Act. Terminating the rulemaking would preserve those Commission resources needed to continue the rulemaking, but such a short-term benefit would come at a significant cost. Failing to strengthen the set of tools available in support of the Commission's enforcement program against unfair or deceptive consumer reviews or testimonials would deprive it of the benefits outlined above. The Commission seeks comment on this alternative and any potentially reasonable alternative to the proposed Rule.

VIII. Paperwork Reduction Act

In addition to the requirements of Section 22, the Commission must provide in any NPRM the ''information required by the Regulatory Flexibility Act, 5 U.S.C. 601–612, and the Paperwork Reduction Act, 44 U.S.C. 3501–3520, if applicable.'' 16 CFR 1.11(c)(4).

The Paperwork Reduction Act requires the Commission to engage in additional processes and analysis if it proposes to engage in a ''collection of information'' as part of the proposed Rule. 44 U.S.C. 3506. The Commission states that the proposed Rule contains no collection of information.

IX. Regulatory Flexibility Act—Initial Regulatory Flexibility Analysis

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601 *et seq.,* requires an agency to provide an Initial Regulatory Flexibility Analysis (''IRFA'') with a proposed rule and a Final Regulatory Flexibility Analysis (''FRFA'') with a final rule, if any, unless the Commission certifies the proposed rule will not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605. The purpose of a regulatory flexibility analysis is to ensure an agency considers potential impacts on small entities and examines regulatory alternatives that could achieve the regulatory purpose while minimizing burdens on small entities.

The Commission believes the proposed Rule would not have a significant economic impact upon small entities, although it may affect a substantial number of small businesses. The proposed Rule primarily prohibits certain unfair or deceptive acts or practices involving consumer reviews or testimonials and does not impose a recordkeeping or disclosure requirement upon businesses. In addition, the Commission does not anticipate these changes will add significant additional costs to small businesses. Specifically, as discussed in further detail below, the Commission anticipates than an average small business will spend, at most, one hour on compliance review, incurring a cost of $33.23. Therefore, the NPRM imposes no new significant burdens on law-abiding businesses.

Accordingly, based on available information, the Commission certifies the proposed Rule will not have a significant economic impact on a substantial number of small entities. Although the Commission certifies under the RFA that the proposed rule would not, if promulgated, have a significant impact on a substantial number of small entities, the Commission has determined, nonetheless, it is appropriate to publish an IRFA to inquire into the impact of the proposed Rule on small entities. Therefore, the Commission has prepared the following analysis:

A. Description of the Reasons Agency Action Is Being Considered

The Commission describes the reasons for the proposed Rule in Section IV above. The FTC's law enforcement, outreach, and other engagement in this area indicate certain unfair or deceptive acts or practices involving consumer reviews or testimonials are prevalent. The proposed Rule would benefit consumers and legitimate businesses without imposing significant burdens.

B. Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The Commission describes the objectives for the proposed rule in Section IV above. The legal basis for the proposed rule is Section 18 of the FTC Act, 15 U.S.C. 57a, which authorizes the Commission to promulgate, modify, and repeal trade regulation rules that define with specificity acts or practices in or affecting commerce that are unfair or deceptive within the meaning of Section 5(a)(1) of the FTC Act, 15 U.S.C. 45(a)(1).

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rule Will Apply

The proposed Rule would impact all small entities that currently have, or might potentially accrue, consumer reviews or testimonials. It would also impact small entities that use celebrity testimonials or have a social media presence. It is likely the proposed rule would primarily affect businesses that sell products or services directly to consumers. For example, the proposed Rule is less likely to impact small entities that manufacture niche raw materials for other businesses or small agricultural firms that do not sell directly to consumers. Nevertheless, for a conservative estimate of total costs, the NPRM assumes the proposed Rule would impact all industry classes of small entities.

As described in Part V.A.2.a., there are approximately 33.19 million small businesses in the United States. Prior research has found 74 percent of small businesses have at least one Google review. It is possible that, across all platforms (beyond Google reviews), a higher percentage of small businesses have consumer reviews or testimonials, celebrity testimonials, or a social media presence. The Commission does not have the appropriate data to refine this estimate. Therefore, the best estimate is 24.56 million (74 percent × 33.19 million) small businesses would be impacted by the proposed Rule. The Commission seeks comment on the estimated number of small business entities for which the proposed Rule would have a significant economic impact.

D. Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements

The proposed contains no reporting or recordkeeping requirements. Therefore, many legitimate businesses are likely to incur no additional compliance costs with the proposed Rule.

As described in Section V.A.2.a, a cautious firm may elect to undertake additional compliance review due to the enhanced penalties associated with potential rule violations (relative to *de novo* violations of Section 5 of the FTC Act). If every small business impacted by the proposed Rule conducted one hour of compliance review, each firm would incur $33.23 of compliance costs, which reflects the estimated hourly

earnings of a small business owner.[251] Therefore, under the conservative assumption of heightened compliance review for all small businesses, costs to small businesses would total $816.13 million (24.56 million × $33.23). Because it is likely only a minority of small businesses would elect to conduct optional compliance review, total compliance costs for these entities are likely to be significantly lower than this estimate.

E. Identification of Duplicative, Overlapping, or Conflicting Federal Rules

The Commission has not identified any duplication, overlap, or conflict with the proposed Rule. The Commission invites comment and information on this issue.

F. Description of Any Significant Alternatives to the Proposed Rule

The Commission describes alternatives in Section V.A.3. One alternative to the proposed Rule is to rely on the existing tools the Commission currently possesses to combat the specified review and testimonial practices, such as consumer education and enforcement actions brought under Sections 5 and 19 of the FTC Act. The Commission believes promulgation of the proposed Rule would result in greater net benefits to the marketplace while imposing no additional burdens beyond what is required by the FTC Act. As described in further detail in Section V.A., the proposed Rule would not only result in significant benefits to consumers but also improve the competitive environment, particularly for small, independent, or new firms. Therefore, the proposed Rule appears to be superior to this alternative for small entities.

The Commission seeks comment on alternative compliance methods that would reduce the economic impact of the proposed Rule on small entities.

X. Request for Comments

Members of the public are invited to comment on any issues or concerns they believe are relevant or appropriate to the Commission's consideration of the proposed Rule. The Commission requests that factual data on which the comments are based be submitted with the comments. In addition to the issues raised above, the Commission solicits public comment on the specific questions identified below. Responses to these questions should be itemized according to the numbered questions in this document. These questions are designed to assist the public and should not be construed as a limitation on the issues on which public comment may be submitted.

General Questions for Comment

When responding to any of the following general questions, please specify the portion(s) of the proposal to which your comment relates.

1. Does the proposed Rule further the Commission's goal of protecting consumers from clearly unfair or deceptive acts or practices involving consumer reviews and testimonials? Why or why not?

2. Should the Commission finalize the proposed Rule as a final rule? Why or why not? How, if at all, should the Commission change the proposed Rule in promulgating a final rule?

3. Please provide comment, including relevant data, statistics, consumer complaint information, or any other evidence, on each different provision of the proposed Rule. Regarding each provision, please include answers to the following questions:

a. What would the provision's impact (including any benefits and costs), if any, be on consumers, governments, and businesses, including existing businesses and those yet to be started? Are there changes that could be made to lessen any such burdens without significantly reducing the benefits?

b. Is the proposed prohibition in the provision clear, meaningful, and appropriate?

c. Should the scope of the proposed prohibition be expanded or narrowed, and, if so, how, and why? How, if at all, should it be improved?

d. Should any final rule keep the proposed prohibition and, if so, why? If not, what alternative proposals should the Commission consider?

4. Does the proposed Rule contain a collection of information?

5. Would the proposed Rule, if promulgated, have a significant economic impact on a substantial number of small entities? If so, how could it be modified to avoid a significant economic impact on a substantial number of small entities?

Specific Questions for Comment

§ 465.1 Definitions

6. Are the proposed definitions clear? Should changes be made to any definitions? Should the scope of any of the proposed definitions be expanded or narrowed, and if so, why?

7. What additional definitions, if any, are needed?

§ 465.2 Fake or False Consumer Reviews, Consumer Testimonials, or Celebrity Testimonials

Proposed § 465.2(b) would prohibit businesses from purchasing a consumer review, or from disseminating or causing the dissemination of a consumer testimonial or celebrity testimonial when the business knew or should have known it was false or fake. Proposed § 465.2(c) would prohibit businesses from procuring a consumer review for posting on a third-party platform or website that the business knew or should have known was false or fake.

8. Is the ''knew or should have known'' standard appropriate for purposes of proposed § 465.2(b) and (c)? Why or why not? One alternative would define a violation as occurring whenever a business engages in a deceptive practice with respect to a review or testimonial if the business ''knew or could have known'' that the review or testimonial was deceptive. Should the Commission adopt this alternative? Why or why not? Should the Commission adopt a different knowledge requirement, and if so, what should it be and why? Should there be no knowledge requirement at all for proposed § 465.2(b) and (c)? Why or why not?

9. Under what circumstances should a business purchasing or procuring a consumer review know that it is fake or false?

10. Under what circumstances should a business disseminating or causing the dissemination of a consumer testimonial or celebrity testimonial know that it is fake or false?

§ 465.3 Consumer Review Repurposing

Proposed § 465.3 would prohibit businesses from repurposing or causing the repurposing of a consumer review created for one product so that it appears to have been created for a substantially different product.

11. Is the description of ''substantially different product'' appropriate for purposes of this provision? Why or why not? If not, how should it be modified?

12. Under what circumstances do consumers consider products to be significantly different enough that they should not share the same consumer reviews?

§ 465.4 Buying Positive or Negative Consumer Reviews

Proposed § 465.4 would prohibit providing compensation or other incentives in exchange for, or conditioned on, the writing or creation of consumer reviews expressing a particular sentiment.

[251] *See* Payscale, ''Average Small Business Owner Salary,'' *supra* note 250.

12. Should the proposed prohibition distinguish in any way between an explicit and implied condition that a consumer review express a particular sentiment? Why or why not? If so, how should it be addressed?

§ 465.5 Insider Consumer Reviews and Consumer Testimonials

Proposed § 465.5(a) would prohibit an officer or manager of a business from writing or creating a consumer review or consumer testimonial about the business or one of its products or services that fails to have a clear and conspicuous disclosure of the officer's or manager's relationship to the business. Proposed § 465.5(b) would prohibit a business from disseminating a testimonial by an officer, manager, employee, or agent, or any of their relatives, without a clear and conspicuous disclosure of the relationship, when the business knew or should have known the testimonialist's relationship. Proposed § 465.5(c) would prohibit an officer or manager of a business from asking for a consumer review about the business or one of its products or services from a person related to the business, when the solicitor knew or should have known the prospective reviewer's relationship, the request results in a review without a clear and conspicuous disclosure of the relationship, and the requestor failed to advise a disclosure, knew or should have known that a review appeared without such a disclosure and failed to take remedial steps, or encouraged the prospective reviewer not to make such a disclosure.

13. Is it appropriate that proposed § 465.5(a) and (c) apply to ''officers'' and ''managers''? Why or why not? If not, how should either or both prohibitions be modified?

14. Should the term ''managers'' be defined or described? Why or why not? If so, how should it be defined or described?

15. Is it appropriate that proposed § 465.5(a), (b), and (c) are limited to circumstances in which the requisite disclosure is absent? Why or why not? If not, how should any of the prohibitions be modified?

16. Is it appropriate that proposed § 465.5(b) and (c)(1) are limited to circumstances in which the business, officer, or manager knew or should have known of the relationship? Why or why not? One alternative would be to limit the circumstances of a violation to when the business, officer, or manager ''knew or could have known'' of the relationship. Should the Commission adopt this alternative? Why or why not? Should the Commission adopt a different knowledge requirement, and if so, what should it be and why? Should there be no knowledge requirement at all for proposed § 465.5(b) and (c)(1)? Why or why not?

17. Is it appropriate that § 465.5(b) and (c) are limited to testimonials and reviews from officers, managers, employees, agents, or relatives? Why or why not? If not, how should either or both prohibitions be modified?

18. Should the Commission define or otherwise describe the term ''relative''? Why or why not? If so, how should it be defined or described?

19. Is it appropriate that § 465.5(c)(2)(ii) is limited to circumstances in which the requestor knew or should have known that the review appeared without such a disclosure? Why or why not? One alternative would be to limit the circumstances of a violation to when the requestor ''knew or could have known'' that the review appeared without such a disclosure. Should the Commission adopt this alternative? Why or why not? Should the Commission adopt a different knowledge requirement, and if so, what should it be and why? Should there be no knowledge requirement at all for proposed § 465.5(c)(2)(ii)? Why or why not?

§ 465.7 Review Suppression

Proposed § 465.7(a) would prohibit anyone from using an unjustified legal threat or a physical threat, intimidation, or false accusation in an attempt to remove or prevent a negative consumer review. Proposed § 465.7(b) would prohibit a merchant from misrepresenting that the consumer reviews displayed on its website or platform represent most or all the reviews submitted when it is suppressing reviews based upon their ratings or their negativity.

20. Is it appropriate that proposed § 465.7(a) focuses on the specific types of listed threats or activities? Why or why not? If not, how should it be modified?

21. Is the definition of ''unjustified legal threat'' sufficiently clear? Why or why not? If not, how should it be modified?

22. Is it appropriate that proposed § 465.7(b) is limited to circumstances in which reviews are being suppressed based on rating or negativity? Why or why not? If not, how should it be modified?

23. Is it appropriate that proposed § 465.7(b) is limited to the misrepresentations described therein? Why or why not? If not, how should it be modified?

XI. Comment Submissions

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 29, 2023. Write ''Consumer Reviews and Testimonials NPRM, R311003'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the website *https://www.regulations.gov.*

Because of the agency's heightened security screening, postal mail addressed to the Commission will be subject to delay. We strongly encourage you to submit your comments online through the *https://www.regulations.gov* website. To ensure that the Commission considers your online comment, please follow the instructions on the web-based form.

If you file your comment on paper, write ''Consumer Reviews and Testimonials NPRM, R311003'' on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW, Suite CC–5610 (Annex F), Washington, DC 20580. If possible, please submit your paper comment to the Commission by overnight service.

Because your comment will be placed on the public record, you are solely responsible for making sure that your comment does not include any sensitive or confidential information. In particular, your comment should not contain sensitive personal information, such as your or anyone else's Social Security number; date of birth; driver's license number or other state identification number or foreign country equivalent; passport number; financial account number; or credit or debit card number. You are also solely responsible for making sure your comment does not include any sensitive health information, such as medical records or other individually identifiable health information. In addition, your comment should not include any ''[t]rade secret or any commercial or financial information which . . . is privileged or confidential''—as provided in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2)—including, in particular, competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

Comments containing material for which confidential treatment is requested must be filed in paper form, must be clearly labeled ''Confidential,''

and must comply with FTC Rule 4.9(c), 16 CFR 4.9(c). In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c). Your comment will be kept confidential only if the General Counsel grants your request in accordance with the law and the public interest. Once your comment has been posted publicly at *https://www.regulations.gov*—as legally required by FTC Rule 4.9(b), 16 CFR 4.9(b)—we cannot redact or remove your comment, unless you submit a confidentiality request that meets the requirements for such treatment under FTC Rule 4.9(c), and the General Counsel grants that request.

Visit the FTC website to read this document and the news release describing it. The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments it receives on or before September 29, 2023. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *https://www.ftc.gov/siteinformation/privacypolicy.*

XII. Communications by Outside Parties to the Commissioners or Their Advisors

Pursuant to FTC Rule 1.18(c)(1)(i)–(ii), the Commission has determined that communications with respect to the merits of this proceeding from any outside party to any Commissioner or Commissioner advisor shall be subject to the following treatment. Written communications and summaries or transcripts of oral communications shall be placed on the rulemaking record if the communication is received before the end of the public comment period in response to this NPRM. They shall be placed on the public record if the communication is received later. Unless the outside party making an oral communication is a member of Congress, such communications are permitted only if advance notice is published in the Weekly Calendar and Notice of Sunshine Meetings.[252]

List of Subjects in 16 CFR Part 465

Advertising.

■ For the reasons set forth above, the Federal Trade Commission proposes to amend title 16, chapter I, subchapter D of the Code of Federal Regulations by adding part 465 to read as follows:

PART 465—RULE ON THE USE OF CONSUMER REVIEWS AND TESTIMONIALS

Sec.

465.1 Definitions.
465.2 Fake or False Consumer Reviews, Consumer Testimonials, or Celebrity Testimonials.
465.3 Consumer Review Repurposing.
465.4 Buying Positive or Negative Consumer Reviews.
465.5 Insider Consumer Reviews and Consumer Testimonials.
465.6 Company-Controlled Review websites or Entities.
465.7 Review Suppression.
465.8 Misuse of Fake Indicators of Social Media Influence.
465.9 Severability.

Authority: 15 U.S.C. 57a.

§ 465.1 Definitions.

(a) *Business* means an individual, partnership, corporation, or any other commercial entity that sells products or services.

(b) *Celebrity testimonial* means an advertising or promotional message (including verbal statements, demonstrations, or depictions of the name, signature, likeness, or other identifying personal characteristics of an individual) that consumers are likely to believe reflects the opinions, beliefs, or experiences of a well-known person who purchased, used, or otherwise had experience with a product, service, or business.

(c) *Clear and conspicuous* means that a required disclosure is easily noticeable (*i.e.,* difficult to miss) and easily understandable by ordinary consumers, including in all of the following ways:

(1) In any communication that is solely visual or solely audible, the disclosure must be made through the same means through which the communication is presented. In any communication made through both visual and audible means, such as a television advertisement, the disclosure must be presented simultaneously in both the visual and audible portions of the communication even if the representation requiring the disclosure is made in only one means.

(2) A visual disclosure, by its size, contrast, location, the length of time it appears, and other characteristics, must stand out from any accompanying text or other visual elements so that it is easily noticed, read, and understood.

(3) An audible disclosure, including by telephone or streaming video, must be delivered in a volume, speed, and cadence sufficient for ordinary consumers to easily hear and understand it.

(4) In any communication using an interactive electronic medium, such as social media or the internet, the disclosure must be unavoidable. A disclosure is not clear and conspicuous if a consumer must take any action, such as clicking on a hyperlink or hovering over an icon, to see it.

(5) The disclosure must use diction and syntax understandable to ordinary consumers and must appear in each language in which the representation that requires the disclosure appears.

(6) The disclosure must comply with these requirements in each medium through which it is received, including all electronic devices and face-to-face communications.

(7) The disclosure must not be contradicted or mitigated by, or inconsistent with, anything else in the communication.

(8) When the representation or sales practice targets a specific audience, such as children, the elderly, or the terminally ill, ''ordinary consumers'' includes members of that group.

(d) *Consumer review* means a consumer's evaluation, or a purported consumer's evaluation, of a product, service, or business that is submitted by the consumer or purported consumer and that is published to a website or platform dedicated in whole or in part to receiving and displaying such evaluations. For the purposes of this Rule, consumer reviews include consumer ratings regardless of whether they include any text or narrative.

(e) *Consumer testimonial* means an advertising or promotional message (including verbal statements, demonstrations, or depictions of the name, signature, likeness, or other identifying personal characteristics of an individual) that consumers are likely to believe reflects the opinions, beliefs, or experiences of a consumer who has purchased, used, or otherwise had experience with a product, service, or business.

(f) *Indicators of social media influence* means any metrics used by the public to make assessments of an individual's or entity's social media influence, such as followers, friends, connections, subscribers, views, plays, likes, reposts, and comments.

(g) *Officers* include owners, executives, and managing members of a business.

(h) *Purchase a consumer review* means to provide something of value, such as money, goods, or another review, in exchange for a consumer review.

[252] *See* 15 U.S.C. 57a(i)(2)(A); 16 CFR 1.18(c).

(i) *Reviewer* means the author or purported author of a consumer review.

(j) *Substantially different product* means a product that differs from another product in one or more material attributes other than color, size, count, or flavor.

(k) *Testimonialist* means the person giving or purportedly giving a consumer testimonial or celebrity testimonial.

(l) An *unjustified legal threat* is a threat to initiate or file a baseless legal action, such as an action for defamation that challenges truthful speech or matters of opinion.

§ 465.2 Fake or False Consumer Reviews, Consumer Testimonials, or Celebrity Testimonials.

(a) It is an unfair or deceptive act or practice and a violation of this Rule for a business to write, create, or sell a consumer review, consumer testimonial, or celebrity testimonial:

(1) by a reviewer or testimonialist who does not exist;

(2) by a reviewer or testimonialist who did not use or otherwise have experience with the product, service, or business that is the subject of the review or testimonial; or

(3) that materially misrepresents, expressly or by implication, the reviewer's or testimonialist's experience with the product, service, or business that is the subject of the review or testimonial.

(b) It is an unfair or deceptive act or practice and a violation of this Rule for a business to purchase a consumer review, or to disseminate or cause the dissemination of a consumer testimonial or celebrity testimonial, about the business or one of its products or services, which the business knew or should have known:

(1) was by a reviewer or testimonialist who does not exist;

(2) was by a reviewer or testimonialist who did not use or otherwise have experience with the product, service, or business that is the subject of the review or testimonial; or

(3) materially misrepresents, expressly or by implication, the reviewer's or testimonialist's experience with the product, service, or business that is the subject of the review or testimonial.

(c) It is an unfair or deceptive act or practice and a violation of this Rule for a business to procure a consumer review for posting on a third-party platform or website, about the business or one of its products or services, which the business knew or should have known:

(1) was by a reviewer who does not exist;

(2) was by a reviewer who did not use or otherwise have experience with the product, service, or business that is the subject of the review or testimonial; or

(3) materially misrepresents, expressly or by implication, the reviewer's experience with the product, service, or business that is the subject of the review.

§ 465.3 Consumer Review Repurposing.

It is an unfair or deceptive act or practice and a violation of this Rule for a business to use or repurpose a consumer review written or created for one product so that it appears to have been written or created for a substantially different product, or to cause such use or repurposing.

§ 465.4 Buying Positive or Negative Consumer Reviews.

It is an unfair or deceptive act or practice and a violation of this Rule for a business to provide compensation or other incentives in exchange for, or conditioned on, the writing or creation of consumer reviews expressing a particular sentiment, whether positive or negative, regarding the product, service, or business that is the subject of the review.

§ 465.5 Insider Consumer Reviews and Consumer Testimonials.

It is an unfair or deceptive act or practice and a violation of this Rule for:

(a) an officer or manager of a business to write or create a consumer review or consumer testimonial about the business or one of its products or services that fails to have a clear and conspicuous disclosure of the officer's relationship to the business;

(b) a business to disseminate or cause the dissemination of a consumer testimonial about the business or one of its products or services by one of its officers, managers, employees, or agents, or any of their relatives which fails to have a clear and conspicuous disclosure of the testimonialist's relationship to the business or to the officer, manager, employee, or agent, when the business knew or should have known the testimonialist's relationship to the business or to one of its officers, employees, or agents; or

(c) an officer or manager of a business to solicit or demand a consumer review about the business or one of its products or services from an employee, from an agent, or from a relative of any such officer, manager, employee, or agent, when:

(1) the officer or manager knew or should have known the prospective reviewer's relationship to the business or to one of its officers, managers, employees, or agents,

(2) the officer or manager:

(i) did not instruct the prospective reviewer to disclose clearly and conspicuously that relationship,

(ii) knew or should have known that such a review appeared without such a disclosure and failed to take remedial steps, or

(iii) encouraged the prospective reviewer not to make such a disclosure, and

(3) the solicitation or demand results in the prospective reviewer writing or creating such a review without such a disclosure.

§ 465.6 Company-Controlled Review websites or Entities.

It is an unfair or deceptive act or practice and a violation of this Rule for a business to represent, expressly or by implication, that a website, organization, or entity that it controls, owns, or operates provides independent reviews or opinions about a category of businesses, products, or services including the business or one or more of its products or services.

§ 465.7 Review Suppression.

It is an unfair or deceptive act or practice and a violation of this Rule:

(a) for anyone to use an unjustified legal threat or a physical threat, intimidation, or false accusation in an attempt to prevent a consumer review or any portion thereof from being written or created or cause a consumer review or any portion thereof to be removed; or

(b) for a business to misrepresent, expressly or by implication, that the consumer reviews of one or more of its products or services displayed on its website or platform represent most or all the reviews submitted to the website or platform when reviews are being suppressed (*i.e.,* not displayed) based upon their ratings or their negativity. For purposes of this paragraph, a review is not considered suppressed based upon rating or negativity if the suppression occurs because of any of the following reasons, so long as the criteria for withholding reviews are applied to all reviews submitted without regard to the favorability of the review:

(1) the review contains:

(i) trade secrets or privileged or confidential commercial or financial information,

(ii) libelous, harassing, abusive, obscene, vulgar, or sexually explicit content,

(iii) the personal information or likeness of another person,

(iv) content that is discriminatory with respect to race, gender, sexuality, ethnicity, or another protected class, or

(v) content that is clearly false or misleading;

(2) the seller reasonably believes the review is fake; or

(3) the review is wholly unrelated to the products or services offered by or available at the website or platform.

§ 465.8 Misuse of Fake Indicators of Social Media Influence.

It is an unfair or deceptive act or practice and a violation of this Rule for anyone to:

(a) sell or distribute fake indicators of social media influence that can be used by persons or businesses to misrepresent their influence or importance for a commercial purpose; or

(b) purchase or procure fake indicators of social media influence to misrepresent their influence or importance for a commercial purpose.

§ 465.9 Severability.

The provisions of this part are separate and severable from one another. If any provision is stayed or determined to be invalid, the remaining provisions shall continue in effect.

By direction of the Commission.

April J. Tabor,

Secretary.

[FR Doc. 2023–15581 Filed 7–28–23; 8:45 am]

BILLING CODE 6750–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 203

[Docket No. FR–6353–P–01]

RIN 2502–AJ66

Modernization of Engagement With Mortgagors in Default

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, Department of Housing and Urban Development, HUD.

ACTION: Proposed rule.

SUMMARY: HUD's regulations require that mortgagees of Federal Housing Administration (FHA) insured single family mortgages (mortgagees) meet in person, or make a reasonable effort to meet in person, with mortgagors who are in default on their mortgage payments. This rule proposes to modernize this requirement by updating HUD's regulation to better align with advances in electronic communication technology and mortgagor engagement preferences, while preserving consumer protections. Specifically, this rule proposes to update HUD's current in-person, face-to-face meeting requirements by permitting mortgagees to utilize methods of communication most likely to receive a response from the mortgagor as determined by the Secretary, including electronic and other remote communication methods, such as telephone calls or video calls, to meet with mortgagors who are in default on their mortgage payments. This proposed rule would also expand the meeting requirement to all mortgagors in default, including mortgagors who do not reside in the mortgaged property and those with a mortgaged property not within 200 miles of their mortgagee, its servicer, or a branch office of either.

DATES: *Comment Due Date:* September 29, 2023.

ADDRESSES: There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. Electronic Submission of Comments. Comments may be submitted electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make comments immediately available to the public. Comments submitted electronically through *www.regulations.gov* can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that website to submit comments electronically.

2. Submission of Comments by Mail. Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW, Room 10276, Washington, DC 20410–0500.

Note: To receive consideration as a public comment, comments must be submitted through one of the two methods specified above.

Public Inspection of Public Comments. HUD will make all properly submitted comments and communications available for public inspection and copying during regular business hours at the above address. Due to security measures at the HUD Headquarters building, you must schedule an appointment in advance to review the public comments by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.* Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Graham Mayfield, Acting Director, Office of Single Family Asset Management, Department of Housing and Urban Development, 451 7th Street SW, Room 9278, Washington, DC 20410, telephone 202–768–2838 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: First codified in 1976, HUD's regulations at 24 CFR 203.604 require mortgagees to meet in person, or make a reasonable effort to meet in person, with mortgagors who are in default on their mortgage payment. This requirement for an in-person meeting with the mortgagor, commonly referred to as the ''face-to-face meeting'' requirement, originated during a time when mortgage lending and servicing activities were conducted in person at locations in the local communities a mortgagee served. At that time, a ''face-to-face'' meeting was the most effective way to discuss and facilitate loss mitigation options because knowledgeable mortgagee staff were available at locations near the mortgaged property. Beginning in the mid-1990s, many mortgagees began consolidating origination and servicing activities in centralized locations. Today, many mortgagees have a national presence and often employ a single national servicing center or a limited number of regional servicing centers, operate without retail places of business altogether, and tend to conduct origination and servicing activities with employees and clients not being in close physical proximity. In addition, mortgagors prefer to conduct business online or through other remote methods. This proposed rule would permit the use of electronic and other remote communication methods to make it more convenient for mortgagors in default to participate in meetings with their mortgagee.

The current face-to-face meeting requirement also reflects a time when electronic methods for conducting virtual meetings were not widely

available or commonly used. Since 24 CFR 203.604 was last amended, significant advances have been made in the mortgage industry's use of technology and mortgagors' access to such, including smartphones, tablets, and live video communications. Over the years, HUD has updated certain mortgage servicing policies to increase requirements for mortgagees to engage with mortgagors in default on their mortgage payments. To adapt to changing uses of communication technology, in updates to the FHA Single Family Policy Handbook, HUD has expanded its acceptable methods for communicating with mortgagors in default situations, which currently include phone calls, emails, web portals, and other previously used electronic methods.[1] In addition to HUD increasing its requirements for mortgagees to engage with mortgagors in default, the Consumer Financial Protection Bureau (CFPB) servicing regulations at 12 CFR part 1024 and State laws in many jurisdictions require engagement with mortgagors, causing mortgagees to expand their outreach processes to offer mortgagors timely loss mitigation options.

As a result of mortgagees' expanded outreach processes to mortgagors and mortgagors' ability to independently research loss mitigation options, mortgagees reported very few mortgagors who agreed to participate in face-to-face meetings with their mortgagees prior to the COVID–19 pandemic. Data obtained in 2017 and 2018 from members of the Mortgage Bankers Association (MBA) demonstrate mortgagors' limited participation and mortgagees' burdensome costs associated with face-to-face meetings. ''According to data from one mortgagee, the cost of complying with the face-to-face interview requirement in just one year amounted to $3.9 million; however, these efforts resulted in a successful loss mitigation document collection rate of only 5.8 percent for that same period.''[2] As stated in this feedback to HUD, MBA members' ''compliance with this requirement results in a significant commitment of resources by mortgagees, and offers no additional benefits or protections to mortgagors than those already required by other consumer protection servicing regulations.''[3] In 2018, MBA collected additional data from three mortgagees that service the largest FHA-insured portfolios, to further illustrate the limited mortgagor acceptance rate for face-to-face meetings. In the data collected by the MBA, one mortgagee that services over 300,000 FHA-insured mortgages reported hand-delivering over 50,000 face-to-face meeting request letters throughout the year. From those letters, the mortgagee conducted or referred 14 mortgagors for face-to-face meetings, resulting in a 0.028 percent acceptance rate. Another mortgagee that services approximately 610,000 FHA-insured mortgages sent 53,000 letters and conducted 18,000 property visits to deliver face-to-face meeting offers. From that population of sent letters and property visits, no mortgagors accepted the face-to-face meeting offer. A third mortgagee that services approximately 930,000 FHA-insured mortgages conducted 145,000 property visits to deliver face-to-face meeting request letters. From these property visits, 124 mortgagors accepted the face-to-face meeting offers, for a 0.085 percent acceptance rate.[4]

Due to public health concerns around the spread of COVID–19, in March 2020, HUD issued a temporary, partial waiver of the face-to-face meeting requirement found in 24 CFR 203.604, which has been extended on three occasions and remains in effect through December 31, 2023 (collectively, the ''waiver'').[5] Similar to the updates described in this proposed rule, the waiver permitted mortgagees to use alternative methods for contacting mortgagors, including electronic methods of communication, *e.g.,* phone interviews, email, video calling services, and other communication technologies, to meet the requirements of 24 CFR 203.604. With this waiver in place, mortgagees provided over 1.5 million mortgagors in default with loss mitigation assistance during this time. HUD received positive feedback from mortgagees and consumer advocates related to the added flexibility to existing loss mitigation outreach requirements permitted by the waiver.

Mortgagors are demonstrating their preference for interacting with mortgagees through technology. For example, in May 2021, Forbes published the results of a new survey on borrowing and lending conducted by ICE Mortgage Technology, which found the pandemic has permanently changed the way consumers utilize technology and those looking to buy or refinance a home are seeking lenders who offer online tools to complete their mortgage loans from home.[6] According to the survey, ''the importance of lenders offering digital solutions such as online applications during the lending process increased for borrowers in 2020, with 58 percent saying the availability of an online application would affect their lender decision (up from 50 percent in 2018).'' Respondents to the survey who were offered online and/or mobile options by their lenders took advantage of these tools during the mortgage loan process. ''Sixty-one percent of borrowers used an online application in 2020, slightly up from 58 percent in 2018. Sixty-one percent also used an online portal for electronically signing and notarizing documents, compared to 56 percent in 2018.'' As expected, decreased in-person interactions became more important in 2020 due to the COVID–19 pandemic. Only 37 percent of survey respondents in 2018 cited ''no need to meet in person'' as an aspect they preferred about their online application process. ''Whether they had been through the mortgage loan process or not, 63 percent of consumers surveyed believe that an online mortgage process would make buying a home easier than an in-person process.''

Even prior to the COVID–19 pandemic, mortgagees were taking note of the trend of mortgagors' preference for interacting with their mortgagee using technology. As an example, in 2018, the Federal Reserve Bank of New York published research conducted on the role of technology in mortgage lending.[7] While the report focused on mortgage originations by 'FinTech lenders,' which are lenders that offer an application process that can be completed entirely online, similar mortgagor preferences and behaviors are exhibited in mortgage servicing as well. The Federal Reserve Bank of New York's research revealed that ''FinTech lender originations have grown annually by 30 percent from $34bn of total originations in 2010 (2 percent of

[1] FHA Single Family Housing Policy Handbook 4000.1, section III.A.2.h. Early Default Intervention.

[2] MBA letter re: Docket No. FR–6030–N–01, Reducing Regulatory Burden; Enforcing the Regulatory Reform Agenda Under Executive Order 13777, addressed to HUD's Office of General Counsel, Regulations Division, June 14, 2017.

[3] Id.

[4] Correspondence from the MBA to HUD regarding face-to-face meetings, March 14, 2023.

[5] The original waiver issued on March 13, 2020, and subsequent additional temporary, partial waivers to the face-to-face meeting requirement in 24 CFR 203.604 are posted on HUD's Housing Waivers web page, available at *https://www.hud.gov/program_offices/administration/hudclips/waivers.*

[6] Brenda Richardson, Forbes, ''How Digital Technology Changed the Face of the Mortgage Industry,'' May 13, 2021, *https://www.forbes.com/sites/brendarichardson/2021/05/13/how-digital-technology-changed-the-face-of-the-mortgage-industry/?sh=555736f82856.*

[7] Andreas Fuster, Matthew Plosser, Philipp Schnabl, James Vickery, The Role of Technology in Mortgage Lending, Federal Reserve Bank of New York, February 2018, *https://www.newyorkfed.org/medialibrary/media/research/staff_reports/sr836.pdf.*

market) to $161bn in 2016 (8 percent of market). The growth has been particularly pronounced for refinances and for mortgages insured by the Federal Housing Administration (FHA), a segment of the market which primarily serves lower income borrowers.'' The study also found that ''default rates on FinTech mortgages are about 25 percent lower than those for traditional lenders, even when controlling for detailed loan characteristics.''

The evidence shows mortgagees are seeking ways to automate, simplify, and expedite mortgage origination and servicing processes through technological innovation. HUD's proposed updates to the in-person meeting requirement, as described below, align with such advances and better support mortgagor engagement preferences.

I. This Proposed Rule

A. Mortgages Insured Pursuant to 24 CFR Part 203, Except Mortgages Insured on Indian Land Pursuant to Section 248 of the National Housing Act [8]

HUD's current regulations at 24 CFR 203.604 require mortgagees to conduct a face-to-face meeting or make a reasonable effort to arrange such a meeting, with mortgagors who are in default on their mortgage payments. For mortgages insured pursuant to 24 CFR part 203, except mortgages insured on Indian Land pursuant to section 248 of the National Housing Act, HUD proposes to make it more convenient for mortgagors in default to meet with their mortgagee by updating the requirement that mortgages must have a face-to-face meeting requirement with mortgagors to permit mortgagees to meet with mortgagors who are in default on their mortgage payments either through a face-to-face meeting or other communication methods as determined by the Secretary, including electronic or other remote communication methods such as telephone or video calls. Additionally, given these expanded methods of engagement permitted and recent FHA policy updates that make loss mitigation options available to mortgagors who do not reside in the mortgaged property, HUD proposes to eliminate two of the exemptions to the meeting with the mortgagor requirement currently found in 24 CFR 203.604(c). The exemptions proposed to be eliminated are that (1) mortgagees are not required to meet with a mortgagor if the mortgagor does not reside in the mortgaged property and (2) a meeting with the mortgagor is not required if the mortgaged property is not within 200 miles of the mortgagee, its servicer, or a branch office of either. Finally, the proposed updates would amend the definition of a ''reasonable effort'' to arrange a meeting with the mortgagor to align with the proposed updates regarding the addition of the option to use electronic or other remote communication methods as determined by the Secretary to conduct a meeting with the mortgagor.

HUD believes that these proposed updates to 24 CFR 203.604 would improve mortgagee engagement with mortgagors, reduce the cost of mortgage default servicing, and align HUD's regulations with advancements made in electronic communication technology and in mortgagor communication preferences, while preserving consumer protections. According to the survey results published by Forbes in 2021, discussed above, ''online applications and online portals are currently the digital tools most commonly offered by lenders, with more than 9 in 10 offering both options to borrowers (91 percent). Of lenders who offer online applications, 38 percent said that more than 80 percent of their applications were completed online in 2020, while 60.4 percent said that more than half of all loan applications were submitted online. Homeowners who used an online application appreciated the simpler application process (55 percent) reduced time to close (53 percent) and fewer in-person interactions (49 percent).'' [9]

While HUD's proposed updates would update the acceptable method(s) that mortgagees may use to meet with a mortgagor in default, the purpose for the meeting remains the same. The meeting requirement is the mortgagor's opportunity to meet directly with trained mortgagee staff who can provide information about FHA loss mitigation options to assist the mortgagor in curing the default episode and bringing the FHA-insured mortgage current or otherwise avoiding foreclosure. Generally, mortgagors are unfamiliar with FHA's home retention loss mitigation options and do not understand what a short-term forbearance, loan modification, or partial claim would entail. Many are also unaware that FHA provides home disposition options for mortgagors in default who are unable to retain their homes and want to avoid foreclosure. In addition to the meeting providing an opportunity for mortgagors in default to meet with knowledgeable mortgagee staff who can explain all loss mitigation options available, the meeting also provides the opportunity for the mortgagee to begin collecting the information needed to evaluate mortgagors for FHA's loss mitigation options.

With the addition of other Secretary approved options for mortgagees to conduct the meeting with the mortgagor, the proposed updates would permit mortgagees to utilize more flexible communication and scheduling options to meet with the mortgagor at the mortgagor's convenience. Additionally, the proposed updates would reduce the expense incurred by mortgagees and the difficulties associated with making at least one trip to see the mortgagor at the mortgaged property to schedule a meeting with the mortgagor.

HUD is committed to requiring mortgagees to engage with mortgagors in default to provide information about loss mitigation options available to mitigate losses to HUD's Mutual Mortgage Insurance Fund and avoid foreclosure. This proposed rule would maintain the requirement that mortgagees meet, or make a reasonable effort to meet, with mortgagors who are in default on their mortgage by updating HUD's regulations to align with advances in electronic communication technology and changes in mortgagor engagement preferences, while preserving consumer protections. This proposed rule would also expand the meeting requirement to all mortgagors in default, including mortgagors who do not reside in the mortgaged property and those with a mortgaged property that is not within 200 miles of the mortgagee, its servicer, or a branch office of either. A paragraph-by-paragraph summarized explanation and description of the proposed updates to 24 CFR 203.604 are outlined immediately below.

Proposed 24 CFR 203.604(a)

HUD proposes to add language to paragraph (a), currently reserved, to clarify that paragraph (a) applies to all mortgages insured pursuant to 24 CFR part 203, except mortgages insured on Indian Land pursuant to section 248 of

[8] This section describes proposed requirements for mortgages insured pursuant to 24 CFR part 203, except mortgages insured on Indian Land pursuant to section 248 of the National Housing Act. Due to statutory requirements, the in-person, face-to-face meeting requirement found at 24 CFR 203.604 for mortgages insured pursuant to section 248 of the National Housing Act will remain in place. This proposed rule proposes certain other changes to 24 CFR 203.604 regarding mortgages insured pursuant to section 248 of the National Housing Act, those proposed changes are described later in this preamble.

[9] Brenda Richardson, Forbes, How Digital Technology Changed the Face of the Mortgage Industry, May 13, 2021, *https://www.forbes.com/sites/brendarichardson/2021/05/13/how-digital-technology-changed-the-face-of-the-mortgage-industry/?sh=555736f82856.*

the National Housing Act. As described below, the proposed text in paragraph (b) would apply to mortgages insured on Indian Land pursuant to section 248 of the National Housing Act (Section 248 Mortgages on Indian Land).

Proposed 24 CFR 203.604(a)(1)

HUD proposes to add paragraph (a)(1) to § 203.604, which would largely consist of language currently found in § 203.604(b). The proposed paragraph (a)(1) would update the requirement that mortgagees must meet ''face-to-face'' with mortgagors. As discussed earlier, the proposed updates would require that the mortgagee meet with the mortgagor either through a face-to-face meeting or by using other communication methods as determined by the Secretary. These may include electronic or other remote communication methods such as telephone or video calls. Specific guidance detailing acceptable communication methods that may be used for conducting the meeting with mortgagors in default, in addition to a face-to-face meeting option, will be established through a Mortgagee Letter or an update to the FHA Single Family Housing Policy Handbook 4000.1.

In addition, HUD proposes to eliminate reference to Section 248 Mortgages on Indian Land, as listed in the current paragraph (b), because HUD proposes to describe the face-to-face meeting requirements for Section 248 Mortgages on Indian Land in a revised paragraph (b), as described below. Finally, HUD proposes to eliminate reference to mortgages authorized by section 203(q) of the National Housing Act, as listed in the current paragraph (b), because section 203(q) of the National Housing Act was repealed on July 30, 2008.

Proposed 24 CFR 203.604(a)(1)(i)

HUD proposes to add paragraph (a)(1)(i) to § 203.604, which would largely consist of language currently found in § 203.604(b). The proposed paragraph (a)(1)(i) would clarify that mortgagees are also required to meet with a mortgagor when default occurs on a repayment plan.

Proposed 24 CFR 203.604(a)(2)

HUD proposes to add paragraph (a)(2) to § 203.604, which would replace § 203.604(c), while using most of the language from the current paragraph (c). The proposed paragraph (a)(2), as changed from the language currently in paragraph (c), would remove reference to a ''face-to-face'' meeting with mortgagors, consistent with and as described in the proposed paragraph (a)(1).

In proposed paragraph (a)(2), HUD also proposes to eliminate certain exemptions from the meeting with the mortgagor rule, which are currently detailed in paragraph (c). The two exemptions proposed to be eliminated from the current paragraph (c) are (1) a meeting with the mortgagor is not required if the mortgagor does not reside in the mortgaged property, and (2) a meeting with the mortgagor is not required if the mortgaged property is not within 200 miles of the mortgagee, its servicer, or a branch office of either.

Loss mitigation options were previously unavailable to mortgagors who do not reside in the mortgaged property. As the availability of loss mitigation has expanded to include these mortgagors, it is appropriate to require that mortgagees meet the same engagement requirements as for mortgagors who occupy the mortgaged property. The current exemption for mortgagors with properties not within 200 miles of the mortgagee was intended to prevent an unreasonable burden on the mortgagor and mortgagee. HUD proposes to eliminate these two exemptions to expand the requirement that mortgagees meet, or make a reasonable effort to meet, with all mortgagors in default on their mortgage payments. These two current exemptions would generally be unnecessary given the proposal that mortgagees would be permitted to meet with mortgagors via electronic communication methods.

Proposed 24 CFR 203.604(a)(3)

HUD proposes to add paragraph (a)(3) to § 203.604, which would replace the language currently found in paragraph (d). The proposed paragraph (a)(3), as changed from the language currently in paragraph (d), would remove reference to a ''face-to-face'' meeting with mortgagors, consistent with and as described in the proposed paragraph (a)(1). In proposed paragraph (a)(3), HUD also proposes to redefine what constitutes a mortgagee's ''reasonable effort'' to arrange a meeting with a mortgagor as required by § 203.604. For the purposes of the proposed paragraph (a)(3), HUD proposes to remove the language currently found in paragraph (d) that a ''reasonable effort'' consists of the mortgagee sending the mortgagor at least one letter certified by the Postal Service and that the mortgagee must make at least one trip to the mortgaged property in an effort to arrange a meeting with the mortgagor. Instead, HUD proposes to define a ''reasonable effort'' to arrange a meeting with a mortgagor to require, at a minimum, two verifiable attempts to contact the mortgagor utilizing methods determined by the Secretary. The definition for a ''verifiable attempt'' will be established through Mortgagee Letter or an update to the FHA Single Family Housing Policy Handbook 4000.1.

HUD specifically seeks public comment on its proposed revisions to what constitutes a ''reasonable effort,'' including what should constitute a ''verifiable attempt.''

B. Mortgages Insured on Indian Land Pursuant to Section 248 of the National Housing Act

Due to statutory requirements, HUD is leaving the in-person, face-to-face meeting requirement found in 24 CFR 203.604 in place for Section 248 Mortgages on Indian Land. Unlike other single-family mortgage insurance programs regulated under 24 CFR part 203, the National Housing Act specifically requires that mortgagees conduct a face-to-face meeting with mortgagors who are in default on their mortgage payments for Section 248 Mortgages on Indian Land. Given these statutory requirements, HUD is proposing no substantive updates to the requirements for Section 248 Mortgages on Indian Land found in 24 CFR 203.604; however, HUD is proposing updates to the text of 24 CFR 203.604 to reorganize the paragraph structure and to make the requirements for Section 248 Mortgages on Indian Land easier to understand.

A summarized explanation and description of the proposed updates are outlined immediately below.

Proposed 24 CFR 203.604(b)

HUD proposes to create a new paragraph (b) to § 203.604, which will replace the language currently found in paragraph (e). The proposed paragraph (b) would detail the face-to-face meeting requirements for Section 248 Mortgages on Indian Land. While the language in the proposed paragraph (b) will appear expanded from the text currently in paragraph (e), substantively, the requirements in the proposed paragraph (b) would be the same as the requirements that currently exist for Section 248 Mortgages on Indian Land found in the current paragraph (e). The text in the proposed paragraph (b) appears expanded from the current paragraph (e) because the current paragraph (e) cross references the existing face-to-face meeting requirements that are detailed in the current paragraphs (b), (c), and (d) of § 203.604. Given the proposed updates to the meeting with the mortgagor

requirement for mortgages insured pursuant to 24 CFR part 203, except mortgages insured on Indian Land pursuant to section 248 of the National Housing Act, described above, the face-to-face meeting requirements for Section 248 Mortgages on Indian Land would be directly incorporated into the proposed paragraph (b). Additionally, various wording changes from the current paragraph (e) would be made in the proposed paragraph (b) to ensure clarity and consistency in word choice throughout § 203.604.

III. Findings and Certifications

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. The updates described in this proposed rule would be limited to permitting mortgagees to communicate with mortgagors who are in default on their mortgage methods via electronic or other remote communication methods as determined by the Secretary rather than in-person. Since mortgagees are already required to communicate with these mortgagors, this proposed rule would, if finalized, only alter the options for how mortgagees communicate with this population of mortgagors. If there is an economic effect on mortgagees, it would fall equally on all mortgagees. Further, HUD anticipates that the proposed rule, if finalized, would have a net positive economic impact on mortgagees by reducing the expenses associated with making an in-person visit to a mortgagor's property to comply with the requirements of 24 CFR 203.604.

Environmental Impact

This proposed rule does not direct, provide for assistance or loan and mortgage insurance for, or otherwise govern or regulate, real property acquisition, disposition, rehabilitation, alteration, demolition, or new construction, or establish, revise, or provide for standards for construction or construction materials, manufactured housing, or occupancy. Accordingly, under 24 CFR 50.19(c)(1), this proposed rule is categorically excluded from environmental review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321).

Executive Order 13132, Federalism

Executive Order 13132 (Federalism) prohibits an agency from publishing any rule that has federalism implications if the rule either: (i) imposes substantial direct compliance costs on State and local governments and is not required by statute, or (ii) preempts State law, unless the agency meets the consultation and funding requirements of section 6 of the Executive Order. This proposed rule 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.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and Tribal governments, and on the private sector. This proposed rule would not impose any Federal mandates on any State, local, or Tribal governments, or on the private sector, within the meaning of the UMRA.

List of Subjects in 24 CFR Part 203

Hawaiian Natives, Home improvement, Indians—lands, Loan programs—housing and community development, Mortgage insurance, Reporting and recordkeeping requirements, Solar energy.

For the reasons stated above, HUD proposes to amend 24 CFR part 203 as follows:

PART 203—SINGLE FAMILY MORTGAGE INSURANCE

■ 1. The authority citation for part 203 continues to read as follows:

Authority: 12 U.S.C. 1707, 1709, 1710, 1715b, 1715z–16, 1715u, and 1715z–21; 15 U.S.C. 1639c; 42 U.S.C. 3535(d).

■ 2. Revise § 203.604 to read as follows:

§ 203.604 Contact with the mortgagor.

(a) For mortgages insured pursuant to this part, except those mortgages insured on Indian Land pursuant to section 248 of the National Housing Act:

(1) The mortgagee must conduct a meeting with the mortgagor, or make a reasonable effort to arrange such a meeting, before three full monthly installments due on the mortgage are unpaid and at least 30 days before foreclosure is commenced, or at least 30 days before assignment is requested if the mortgage is insured on Hawaiian home lands pursuant to section 247 of the National Housing Act. The meeting with the mortgagor must be conducted in a manner as determined by the Secretary.

(i) If default occurs on a repayment plan, the mortgagee must conduct a meeting with the mortgagor, or make a reasonable effort to arrange such a meeting, within 30 days after such default.

(ii) [Reserved]

(2) A meeting with the mortgagor is not required if:

(i) The mortgagor has clearly indicated that they will not cooperate in the meeting;

(ii) The mortgagor is on a repayment plan to bring the mortgage current, and the mortgagor is meeting the terms of the repayment plan; or

(iii) A reasonable effort to arrange a meeting with the mortgagor is unsuccessful.

(3) A reasonable effort to arrange a meeting with the mortgagor shall consist of, at a minimum, two verifiable attempts to contact the mortgagor utilizing methods determined by the Secretary.

(b) For mortgages insured on Indian Land pursuant to section 248 of the National Housing Act:

(1) The mortgagee must conduct a face-to-face meeting with the mortgagor, or make a reasonable effort to arrange such a meeting, before three full monthly installments due on the mortgage are unpaid and at least 30 days before assignment is requested.

(i) If default occurs on a repayment plan arranged other than during a face-to-face meeting, the mortgagee must have a face-to-face meeting with the mortgagor, or make a reasonable effort to arrange such a meeting, within 30 days after default or at least 30 days before assignment is requested.

(ii) [Reserved]

(2) A face-to-face meeting is not required if:

(i) The mortgagor has clearly indicated that they will not cooperate in the meeting;

(ii) The mortgagor is on a repayment plan to bring the mortgage current, and the mortgagor is meeting the terms of the repayment plan; or

(iii) A reasonable effort to arrange a meeting with the mortgagor is unsuccessful.

(3) A reasonable effort to arrange a face-to-face meeting with the mortgagor shall include at a minimum, one letter sent to the mortgagor certified by the Postal Service as having been dispatched and at least one trip to see the mortgagor at the mortgaged property. In addition, the mortgagee must document that it has made at least one telephone call to the mortgagor for

the purpose of trying to arrange a face-to-face meeting. The mortgagee may appoint an agent to perform its responsibilities under this paragraph.

(4) The mortgagee must also:

(i) inform the mortgagor that HUD will make information regarding the status and payment history of the mortgagor's loan available to credit bureaus and prospective creditors;

(ii) Inform the mortgagor of other available assistance, if any; and

(iii) Inform the mortgagor of the names and addresses of HUD officials to whom further communications may be addressed.

Julia R. Gordon,

Assistant Secretary for Housing—Federal Housing Commissioner.

[FR Doc. 2023–16128 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–121709–19]

RIN 1545–BP63

Rules for Supervisory Approval of Penalties; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; notice of hearing.

SUMMARY: This document provides a notice of public hearing on proposed regulations regarding supervisory approval of certain penalties assessed by the IRS.

DATES: The public hearing on this proposed regulation has been scheduled for Monday, September 11, 2023, at 10:00 a.m. EST. The IRS must receive speakers' outlines of the topics to be discussed at the public hearing by Friday, August 11, 2023. If no outlines are received by Friday, August 11, 2023, the public hearing will be cancelled.

ADDRESSES: The public hearing is being held in the Auditorium, at the Internal Revenue Service Building, 1111 Constitution Avenue NW, Washington, DC. Due to security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present a valid photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. Participants may alternatively attend the public hearing by telephone.

Send Submissions to CC:PA:LPD:PR (REG–121709–19), Room 5205, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday to CC:PA:LPD:PR (REG–121709–19), Couriers Desk, Internal Revenue Service, 1111 Constitution Avenue NW, Washington, DC 20224 or sent electronically via the Federal eRulemaking Portal at *www.regulations.gov* (IRS REG–121709–19) (preferred).

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, David Bergman, (202) 317–6845; concerning submissions of comments, the hearing and/or to be placed on the building access list to attend the public hearing, call Vivian Hayes (202) 317–6901 (not a toll-free numbers) or by email to *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is the notice of proposed rulemaking (REG–121709–19) that was published in the **Federal Register** on Tuesday, April 11, 2023, (FR 88 21564).

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments at the hearing must submit an outline of the topics to be discussed and the time to be devoted to each topic by August 11, 2023.

A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing, and via the Federal eRulemaking Portal (*www.Regulations.gov*) under the title of Supporting & Related Material. If no outline of the topics to be discussed at the hearing is received by August 11, 2023, the public hearing will be cancelled. If the public hearing is cancelled, a notice of cancellation of the public hearing will be published in the **Federal Register**.

Individuals who want to testify in person at the public hearing must send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG–121709–19 and the language TESTIFY In Person. For example, the subject line may say: Request to TESTIFY In Person at Hearing for REG–121709–19.

Individuals who want to testify by telephone at the public hearing must send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–121709–19 and the language TESTIFY Telephonically. For example, the subject line may say: Request to TESTIFY Telephonically at Hearing for REG–121709–19.

Individuals who want to attend the public hearing in person without testifying must also send an email to *publichearings@irs.gov* to have your name added to the building access list. The subject line of the email must contain the regulation number REG–121709–19 and the language ATTEND In Person. For example, the subject line may say: Request to ATTEND Hearing In Person for REG–121709–19. Requests to attend the public hearing must be received by 5:00 p.m. EST by Wednesday, September 6, 2023.

Individuals who want to attend the public hearing by telephone without testifying must also send an email to *publichearings@irs.gov* to receive the telephone number and access code for the hearing. The subject line of the email must contain the regulation number REG–121709–19 and the language ATTEND Hearing Telephonically. For example, the subject line may say: Request to ATTEND Hearing Telephonically for REG–121709–19. Requests to attend the public hearing must be received by 5:00 p.m. EST by Wednesday, September 6, 2023.

Hearings will be made accessible to people with disabilities. To request special assistance during a hearing please contact the Publications and Regulations Branch of the Office of Associate Chief Counsel (Procedure and Administration) by sending an email to *publichearings@irs.gov* (preferred) or by telephone at (202) 317–6901 (not a toll-free number) by Wednesday, September 6, 2023. Any questions regarding speaking at or attending a public hearing may also be emailed to *publichearings@irs.gov.*

Oluwafunmilayo A. Taylor,

Branch Chief, Publications and Regulations Branch, Associate Chief Counsel, (Procedure and Administration).

[FR Doc. 2023–15985 Filed 7–28–23; 8:45 am]

BILLING CODE 4830–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2023–0342: FRL–11155–01–R10]

Air Plan Approval; Washington; Southwest Clean Air Agency, General Air Quality Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve revisions to the Washington State Implementation Plan (SIP) that were submitted on June 22, 2023, by the Department of Ecology (Ecology) in coordination with the Southwest Clean Air Agency (SWCAA). In 2017, the EPA approved a comprehensive update to *SWCAA 400 General Regulations for Air Pollution Sources* in the SIP, which includes new source review permitting requirements as well as other general requirements for sources regulated under SWCAA's jurisdiction. In this action, the EPA proposes to approve minor updates to SWCAA 400 promulgated since our comprehensive approval in 2017.

DATES: Comments must be received on or before August 30, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2023–0342 at *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Jeff Hunt, EPA Region 10, 1200 Sixth Avenue—Suite 155, Seattle, WA 98101, at (206) 553–0256, or *hunt.jeff@epa.gov.*

Table of Contents

I. Background for Proposed Action
A. WSR 17–11–078—Consolidated Fee Schedule
B. WSR 20–06–003—Adoption of Federal Rules
C. WSR 21–17–054—Revised Statutory Citation and Other Miscellaneous Revisions
II. The EPA's Proposed Action
A. Regulations To Approve and Incorporate by Reference Into the SIP
B. Approved but Not Incorporated by Reference Regulations
III. Incorporation by Reference
IV. Statutory and Executive Order Reviews

I. Background for Proposed Action

On April 10, 2017, the EPA approved a comprehensive update of *SWCAA 400 General Regulations for Air Pollution Sources* in the SIP (82 FR 17136). Under the Washington Clean Air Act, local clean air agencies may adopt equally stringent or more stringent requirements to apply in lieu of Ecology's statewide general air quality regulations for sources regulated under the local agency's jurisdiction, if they so choose.[1] SWCAA's jurisdiction consists of Clark, Cowlitz, Lewis, Skamania, and Wahkiakum counties, with certain exceptions. By statute, SWCAA does not have authority for sources under the jurisdiction of the Energy Facility Site Evaluation Council (EFSEC). See Revised Code of Washington Chapter 80.50. Under the applicability provisions of Washington Administrative Code (WAC) 173–405–012, 173–410–012, and 173–415–012, SWCAA does not have jurisdiction for kraft pulp mills, sulfite pulping mills, and primary aluminum plants. For these sources, Ecology retains statewide, direct jurisdiction. Ecology and EFSEC also retain statewide, direct jurisdiction for issuing permits under the Prevention of Significant Deterioration (PSD) program for major stationary sources in attainment areas. Lastly, SWCAA does not have jurisdiction on Indian reservations and any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. The regulations approved and incorporated by reference into the SIP for SWCAA's specific jurisdiction can be found at 40 CFR 52.2470(c), *Table 8—Additional Regulations Approved for the Southwest Clean Air Agency (SWCAA) Jurisdiction.*

The version of SWCAA 400 approved in the SIP includes updates promulgated by SWCAA effective as of October 9, 2016. SWCAA subsequently promulgated updates to SWCAA 400 effective June 18, 2017, March 21, 2020, and September 10, 2021. Detailed redline/strikeout versions of the regulatory changes are included in the docket under Washington State Register (WSR) documents WSR 17–11–078, WSR 20–06–003, and WSR 21–17–054. In addition, the EPA's evaluation of each WSR document is included in the docket. A summary of the major changes is discussed below.

A. WSR 17–11–078—Consolidated Fee Schedule

Effective June 18, 2017, SWCAA made minor rule changes and consolidated all fees into a single Consolidated Fee Schedule to make it easier for affected parties to locate applicable fees. SWCAA also removed specific fees in individual sections of SWCAA 400, instead redirecting the reader to consult the Consolidated Fee Schedule. Four sections of SWCAA 400 in the currently approved SIP are affected by this change: SWCAA 400–036 *Portable Sources from Other Washington Jurisdictions,* SWCAA 400–072 *Small Unit Notification for Selected Source Categories,* SWCAA 400–074 *Gasoline Transport Tanker Registration,* and SWCAA 400–109 *Air Discharge Permit Applications.*[2] From an EPA approval standpoint, the consolidation of fees and removal of fee amounts from individual sections is not a significant change. In our comprehensive 2017 update of the SIP, we already excluded the fee provisions of SWCAA 400–074(2) and 400–109(4) noting that while the EPA reviews these submissions to confirm adequate authority, the EPA generally does not include local or state agency fees as part of the Washington SIP incorporated by reference in 40 CFR 52.2470(c).[3] Therefore, we are proposing to approve the minor changes to SWCAA 400–036, 400–072, 400–074, and 400–109 removing specific fee amounts and referring the reader to the Consolidated Fee Schedule.[4]

B. WSR 20–06–003—Adoption of Federal Rules

Effective July 1, 2016, Ecology promulgated WAC 173–400–025 *Adoption by Reference,* establishing a single adoption by reference date for all

[1] See proposed rulemaking 82 FR 6413 (January 19, 2017).

[2] See ''wsr_17-11-078_review.pdf'' included in the docket.

[3] See 82 FR 6413 (January 19, 2017) at page 6416 and 6418.

[4] SWCAA subsequently revised section 400–072, effective March 21, 2020, discussed in section I.B of this document. SWCAA also subsequently revised sections 400–036, 400–072, and 400–109, effective September 10, 2021, discussed in section I.C of this document.

Federal rules cited in WAC 173–400 *General Regulations for Air Pollution Sources.* As part of the same revision package, Ecology modified other sections of WAC 173–400 removing specific Federal rule adoption dates, instead cross-referencing WAC 173–400–025. The EPA approved these revisions on October 6, 2016 (81 FR 69385) with a subsequent update to WAC 173–400–025 approved on February 24, 2020 (85 FR 10302).

Effective March 21, 2020, SWCAA promulgated SWCAA 400–025 *Adoption of Federal Rules,* mirroring Ecology's approach. The revision also amends the following sections to remove specific Federal rule adoption dates and instead cross-reference the adoption date in SWCAA 400–025: SWCAA 400–050 *Emission Standards for Combustion and Incineration Units,* SWCAA 400–060 *Emission Standards for General Process Units,* SWCAA 400–072 *Small Unit Notification for Selected Source Categories,* SWCAA 400–105 *Records, Monitoring and Reporting,* SWCAA 400–106 *Emission Testing and Monitoring at Air Contaminant Sources,* SWCAA 400–110 *Application Review Process for Stationary Sources (New Source Review),* SWCAA 400–111 *Requirements for New Sources in a Maintenance Plan Area,* SWCAA 400–171 *Public Involvement,* SWCAA 400–850 *Actual Emissions—Plantwide Applicability Limitation (PAL),* and Appendix A *SWCAA Method 9 Visual Opacity Determination Method.*

We are proposing to approve SWCAA 400–025, which establishes a Federal rule adoption date for citations in SWCAA 400. We are also proposing to approve the minor revisions described above to SWCAA 400–050, 400–060, 400–072, 400–105, 400–106, 400–110, 400–111, 400–171, 400–850, and Appendix A, which refer the reader to SWCAA 400–025.[5] Our proposed approval of these revised sections is subject to the same exclusions cited in our comprehensive 2017 approval and codified in the current approved SIP at 40 CFR 52.2470(c), *Table 8,* with one exception. As part of the update to SWCAA 400–050, the agency added a new subsection (7) related to hospital, medical, and infectious waste incinerators regulated under 40 CFR part 62, subpart HHH, which is outside the scope of the SIP and was not submitted for approval. Therefore, we are proposing to revise the exclusions in 40 CFR 52.2470(c), *Table 8,* to note that SWCAA 400–050(7) is excluded from the approved SIP.

C. WSR 21–17–054—Revised Statutory Citation and Other Miscellaneous Revisions

WSR 21–17–054, effective September 10, 2021, contains numerous revisions to SWCAA 400. Many of the revisions were to sections outside the scope of the SIP, such as SWCAA 400–075 *Emission Standards for Stationary Sources Emitting Hazardous Air Pollutants.* Other changes to SWCAA 400 were submitted as part of a separate SIP revision request, which we will take action on in a separate rulemaking. Sections proposed for approval in this action are SWCAA 400–025 *Adoption of Federal Rules,* SWCAA 400–030 *Definitions,* SWCAA 400–036 *Portable Sources From Other Washington Jurisdictions,* SWCAA 400–050 *Emission Standards for Combustion and Incineration Units,* SWCAA 400–072 *Small Unit Notification for Selected Source Categories,* SWCAA 400–091 *Voluntary Limits on Emissions,* SWCAA *400–105 Records, Monitoring and Reporting,* SWCAA 400–106 *Emission Testing and Monitoring at Air Contaminant Sources,* SWCAA 400–109 *Air Discharge Permit Applications,* SWCAA 400–110 *Application Review Process for Stationary Sources (New Source Review),* SWCAA 400–111 *Requirements for New Sources in a Maintenance Plan Area,* SWCAA 400–112 *Requirements for New Sources in Nonattainment Areas,* SWCAA 400–113 *Requirements for New Sources in Attainment or Nonclassifiable Areas,* SWCAA 400–114 *Requirements for Replacement or Substantial Alteration of Emission Control Technology at an Existing Stationary Source,* SWCAA 400–136 *Maintenance of Emission Reduction Credits in Bank,* SWCAA 400–151 *Retrofit Requirements for Visibility Protection,* SWCAA 400–171 *Public Involvement,* SWCAA 400–230 *Regulatory Actions and Civil Penalties,* SWCAA 400–240 *Criminal Penalties,* SWCAA 400–260 *Conflict of Interest,* SWCAA 400–270 *Confidentiality of Records and Information,* SWCAA 400–280 *Powers of Agency,* and SWCAA 400–810 *Major Stationary Source and Major Modification Definitions.*

Most of the changes proposed for approval in this action are administrative or clarifying in nature. Effective June 11, 2020, the state legislature recodified the Washington Clean Air Act from Revised Code of Washington (RCW) 70.94 to RCW 70A.15. Local air agencies were encouraged to update affected rules to reflect new statutory references by July 1, 2025. This was the sole change affecting SWCAA sections 400–091, 400–112, 400–113, 400–136, 400–230, 400–240, and 400–270. In addition to the recodification, SWCAA made other generally minor changes. A comprehensive redline/strikeout version of WSR 21–17–054 is included in the docket for this action, as well as the EPA's analysis of the revisions proposed for approval in this action. Listed below is a summary of the most significant changes:

- In section 400–025, SWCAA updated the adoption by reference date for Federal regulations cited in other sections of SWCAA 400.
- In section 400–030, SWCAA added a definition for ''diesel,'' made clarifying edits to the definitions for ''distillate oil'' and ''new source'' and revised the definition of ''volatile organic compound'' to match the Federal definition in 40 CFR 51.100(s) effective at the time.[6] We note that in our 2017 approval of section 400–030, SWCAA did not submit, and the EPA did not approve subsection (129) ''Toxic air pollutant'' because the regulation of toxic air pollutants is outside the scope of Clean Air Act (CAA) section 110 requirements for SIPs. With the addition of a new definition for ''diesel'' as subsection (33), subsection (129) is now renumbered to (130). We propose to revise the exclusions in 40 CFR 52.2470(c), *Table 8,* to reflect this change.
- In section 400–036, SWCAA revised requirements for relocation noticing and emission unit registration, adding a provision that portable sources must provide relocation notice upon departure from SWCAA's jurisdiction.
- In section 400–050, SWCAA made minor revisions to subsections (1), (2), and (4). Subsections (3), (5), (6), and (7) are excluded from the current SIP, and SWCAA's submittal requests the EPA retain these exclusions.
- In section 400–072, SWCAA made minor clarifying revisions to the introductory text, as well as to subsections (1), (2), (4), (5)(c), (5)(d), and (5)(e). SWCAA also revised the applicability of subsection (5)(d) from dry cleaning facilities that use petroleum to any dry cleaning facility that uses a solvent other than perchloroethylene. We are proposing to approve the minor updates to SWCAA

[5] SWCAA subsequently revised sections 400–025, 400–050, 400–072, 400–105, 400–110, 400–111, and 400–171 as part of WSR 21–17–054, effective September 10, 2021, discussed in section I.C. of this document.

[6] On February 8, 2023 (88 FR 8226), the EPA revised the definition of Volatile Organic Compounds to exclude (2E)-1,1,1,4,4,4–hexafluorobut-2-ene (HFO1336mzz(E)). Because the revisions EPA is acting on in this action do not include exclusion of this compound, SWCAA's SIP–approved definition is more stringent than the Federal definition, which is acceptable.

400–072 subject to the same exclusions as our comprehensive 2017 update, with one exception. In consultation with the EPA, Ecology and SWCAA did not submit revisions to subsection (5)(b) as part of this SIP revision package. In the interim, the EPA will retain the version of subsection (5)(b) approved as part of our comprehensive 2017 update.

- In section 400–105, SWCAA made minor clarifying edits and added a separate emission inventory submittal deadline for gasoline stations.
- In section 400–106, SWCAA made minor revisions to the source testing requirements in subsection (1).[7]
- In section 400–109, SWCAA added an application procedure for permit extensions in subsection (2)(f) and made minor clarifying edits to other subsections.
- In section 400–110, SWCAA added a new subsection (2)(e) with presumptive application withdrawal provisions, added a new subsection (4)(d) clarifying supersession of previous permits in new permitting actions, revised subsection (6)(d) to add a reference to the portable source provisions in SWCAA 400–036, added a new subsection (12)(b) providing notification and public involvement requirements for reopening for cause actions, and made other clarifying edits.
- In section 400–111, SWCAA made minor administrative edits to update citations and add quotation marks around the defined term ''emission unit'' to match the formatting of other defined terms.
- In section 400–114, SWCAA added a new subsection (2)(b) providing SWCAA with authority to require the owner or operator to employ a level of emission control equivalent to the existing emission control technology when replacing or substantially altering controls, as well as minor administrative edits. SWCAA also added a cross reference to ''T–RACT'' for the regulation of toxic air pollutants which is outside the scope of the SIP.
- In section 400–151, SWCAA made a minor edit to define the acronym ''BART,'' which stands for ''Best Available Retrofit Technology.''
- In section 400–171, SWCAA made minor clarifying edits to the public notice and application notice provisions.
- In section 400–260, SWCAA made clarifying edits including a cross reference to the Federal conflict of interest requirements of Clean Air Act section 128.
- In section 400–280, SWCAA updated and standardized citations for other Revised Code of Washington statutory provisions, in addition to the recodification of the Washington Clean Air Act discussed above.
- In section 400–810, SWCAA corrected internal cross-citations to the definitions.

II. The EPA's Proposed Action

A. Regulations To Approve and Incorporate by Reference Into the SIP

The EPA is proposing to approve and incorporate by reference into the Washington SIP at 40 CFR 52.2470(c)—*Table 8—Additional Regulations Approved for the Southwest Clean Air Agency (SWCAA) Jurisdiction,* the updated SWCAA regulations listed in the table below for sources within SWCAA's jurisdiction. The EPA is also proposing a minor change to the applicability subheading in 40 CFR 52.2470(c)—*Table 8* to more clearly reflect jurisdiction for issuing permits under the PSD program. Our comprehensive 2017 approval stated that Ecology retained statewide, direct jurisdiction for PSD permitting for all major stationary sources not otherwise regulated by EFSEC.[8] However, we neglected to include this clarification to the applicability subheading consistent with other recent approvals in Washington State.[9] Therefore, we are proposing to add this clarification.

UPDATED SOUTHWEST CLEAN AIR AGENCY REGULATIONS

[Applicable in Clark, Cowlitz, Lewis, Skamania and Wahkiakum counties, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	Explanation
SWCAA 400—General Regulations for Air Pollution Sources			
400–025	Adoption of Federal Rules	9/10/21	
400–030	Definitions	9/10/21	Except: 400–030(21) and (130).
400–036	Portable Sources From Other Washington Jurisdictions.	9/10/21	
400–050	Emission Standards for Combustion and Incineration Units.	9/10/21	Except: 400–050(3); 400–050(5); 400–050(6); and 400–050(7).
400–060	Emission Standards for General Process Units.	3/21/20	
400–072	Small Unit Notification for Selected Source Categories.	9/10/21	Except: 400–072(5)(a)(ii)(B); 400–072(5)(d)(ii)(B); 400–072(5)(d)(iii)(A); 400–072(5)(d)(iii)(B); all reporting requirements related to toxic air pollutants; and 400–072(5)(b), which EPA previously approved with a state-effective date of October 9, 2016.
400–074	Gasoline Transport Tanker Registration	6/18/17	Except: 400–074(2).
400–091	Voluntary Limits on Emissions	9/10/21	
400–105	Records, Monitoring and Reporting	9/10/21	Except: Reporting requirements related to toxic air pollutants.
400–106	Emission Testing and Monitoring at Air Contaminant Sources.	9/10/21	Except: 400–106(1)(d) through (g); and 400–106(2).
400–109	Air Discharge Permit Applications	9/10/21	Except: The toxic air pollutant emissions thresholds contained in 400–109(3)(d); 400–109(3)(e)(ii); and 400–109(4).

[7] EPA's proposed approval of changes to sections 400–106, 400–109, 400–110, and 400–111 is subject to the same exclusions identified in our comprehensive 2017 update and codified in the current approved SIP at 40 CFR 52.2470(c), *Table 8.*

[8] See 82 FR 17136 (April 10, 2017) at page 17138.

[9] See 80 FR 23721 (April 29, 2015), 85 FR 22355 (April 22, 2020), 85 FR 36154 (June 15, 2020), and 86 FR 24718 (May 10, 2021).

UPDATED SOUTHWEST CLEAN AIR AGENCY REGULATIONS—Continued

[Applicable in Clark, Cowlitz, Lewis, Skamania and Wahkiakum counties, excluding facilities subject to Energy Facilities Site Evaluation Council (EFSEC) jurisdiction; facilities subject to the Washington Department of Ecology's direct jurisdiction under Chapters 173–405, 173–410, and 173–415 Washington Administrative Code (WAC); Indian reservations; any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction; and the Prevention of Significant Deterioration (PSD) permitting of facilities subject to the applicability sections of WAC 173–400–700.]

State/local citation	Title/subject	State/local effective date	Explanation
400–110	Application Review Process for Stationary Sources (New Source Review).	9/10/21	Except: 400–110(1)(d).
400–111	Requirements for New Sources in a Maintenance Plan Area.	9/10/21	Except: 400–111(7).
400–112	Requirements for New Sources in Nonattainment Areas.	9/10/21	Except: 400–112(6).
400–113	Requirements for New Sources in Attainment or Nonclassifiable Areas.	9/10/21	Except: 400–113(5).
400–114	Requirements for Replacement or Substantial Alteration of Emission Control Technology at an Existing Stationary Source.	9/10/21	
400–136	Maintenance of Emission Reduction Credits in Bank.	9/10/21	
400–151	Retrofit Requirements for Visibility Protection.	9/10/21	
400–171	Public Involvement	9/10/21	Except: 400–171(2)(a)(xii).
400–260	Conflict of Interest	9/10/21	
400–810	Major Stationary Source and Major Modification Definitions.	9/10/21	
400–850	Actual Emissions—Plantwide Applicability Limitation (PAL).	3/21/20	
Appendix A	SWCAA Method 9 Visual Opacity Determination Method.	3/21/20	

B. Approved but Not Incorporated by Reference Regulations

In addition to the regulations proposed for approval and incorporation by reference in section II.A of this document, the EPA reviews and approves state and local clean air agency submissions to ensure they provide adequate enforcement authority and other general authority to implement and enforce the SIP. However, regulations describing such agency enforcement and other general authority are generally not incorporated by reference so as to avoid potential conflict with the EPA's independent authorities. We are proposing to approve revisions, effective September 10, 2021, to SWCAA sections 400–230, 400–240, 400–270, and 400–280 in 40 CFR 52.2470(e), *EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures,* as approved but not incorporated by reference regulatory provisions.

III. Incorporation by Reference

In this document, the EPA is proposing to include in a final rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the updated regulations identified in the table in section II.A and discussed in Section I. of this document. The EPA has made, and will continue to make, these documents generally available through *https://www.regulations.gov* and at the EPA Region 10 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

IV. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Clean Air Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 14094 (88 FR 21879, April 11, 2023);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal

governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

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 Southwest Clean Air Agency 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.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: July 20, 2023.

Casey Sixkiller,

Regional Administrator, Region 10.

[FR Doc. 2023–15750 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 63

[EPA–HQ–OAR–2002–0083; FRL–5919.1–01–OAR]

RIN 2060–AV82

National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing Facilities Technology Review

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is proposing amendments to the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Integrated Iron and Steel Manufacturing Facilities, as required by the Clean Air Act (CAA). To complete the required CAA section 112(d)(6) technology review promulgated on July 13, 2020, the EPA is proposing standards to regulate HAP emissions from five unmeasured fugitive and intermittent particulate (UFIP) sources, some of which are also referred to as ''fugitive'' sources, that are currently not regulated by the NESHAP, as follows: Bell Leaks, Unplanned Bleeder Valve Openings, Planned Bleeder Valve Openings, Slag Pits, and Beaching. Also, for sinter plants we are proposing standards for the following five currently unregulated HAP: carbonyl sulfide (COS), carbon disulfide (CS_2), mercury (Hg), hydrochloric acid (HCl), and hydrogen fluoride (HF); for blast furnace (BF) stoves and basic oxygen process furnaces (BOPFs), we are proposing standards for the following three unregulated pollutants: total hydrocarbons (THC), HCl, and dioxins/furans (D/F); and for BFs, we are proposing standards for the following two unregulated pollutants: THC and HCl. As an update to the technology review, we are proposing to revise the current BOPF shop fugitive 20 percent opacity limit to a 5 percent opacity limit and require specific work practices; revise the current BF casthouse fugitive 20 percent opacity limit to a 5 percent opacity limit; and revise the current standards for D/F and polycyclic hydrocarbon (PAH) for sinter plants. We are also proposing a fenceline monitoring requirement for chromium (Cr), including a requirement that if a monitor exceeds the proposed Cr action level, the facility will need to conduct a root cause analysis and take corrective action to lower emissions. We solicit comments on all aspects of this proposed action.

DATES: *Comments.* Comments must be received on or before September 14, 2023. Under the Paperwork Reduction Act (PRA), comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before August 30, 2023.

Public hearing: If anyone contacts us requesting a public hearing on or before August 7, 2023 by 5:00 p.m. Eastern Time (ET), we will hold a virtual public hearing. See **SUPPLEMENTARY INFORMATION** for information on requesting and registering for a public hearing.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OAR–2002–0083, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Email: a-and-r-docket@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2002–0083 in the subject line of the message.
- *Fax:* (202) 566–9744. Attention Docket ID No. EPA–HQ–OAR–2002–0083.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Docket ID No. EPA–HQ–OAR–2002–0083, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand/Courier Delivery:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal holidays).

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: For questions about this proposed action, contact Phil Mulrine, Sector Policies and Programs Division (D243–02), Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–5289; and email address: *mulrine.phil@epa.gov.*

SUPPLEMENTARY INFORMATION:

Participation in virtual public hearing.

To request a virtual public hearing, contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* If requested, the hearing will be held via virtual platform on August 15, 2023. The hearing will convene at 10:00 a.m. ET and will conclude at 4:00 p.m. ET. The EPA may close a session 15 minutes after the last pre-registered speaker has testified if there are no additional speakers. The EPA will announce further details at *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission.*

If a public hearing is requested, the EPA will begin pre-registering speakers for the hearing no later than 1 business day after a request has been received. To register to speak at the virtual hearing, please use the online registration form available at *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission* or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov.* The last day to pre-register to speak at the hearing will be August 14, 2023. Prior to the hearing, the EPA will post a general agenda that will list pre-registered speakers in approximate order at: *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission.*

The EPA will make every effort to follow the schedule as closely as possible on the day of the hearing; however, please plan for the hearings to run either ahead of schedule or behind schedule.

Each commenter will have 4 minutes to provide oral testimony. The EPA encourages commenters to provide the EPA with a copy of their oral testimony electronically (via email) by emailing it to *mulrine.phil@epa.gov.* The EPA also recommends submitting the text of your oral testimony as written comments to the rulemaking docket.

The EPA may ask clarifying questions during the oral presentations but will not respond to the presentations at that time. Written statements and supporting information submitted during the comment period will be considered with the same weight as oral testimony and supporting information presented at the public hearing.

Please note that any updates made to any aspect of the hearing will be posted online at *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission.* While the EPA expects the hearing to go forward as set forth above, please monitor our website or contact the public hearing team at (888) 372–8699 or by email at *SPPDpublichearing@epa.gov* to determine if there are any updates. The EPA does not intend to publish a document in the **Federal Register** announcing updates.

If you require the services of a translator or a special accommodation such as audio description, please pre-register for the hearing with the public hearing team and describe your needs by August 7, 2023. The EPA may not be able to arrange accommodations without advanced notice.

Docket. The EPA has established a docket for this rulemaking under Docket ID No. EPA–HQ–OAR–2002–0083. All documents in the docket are listed in *https://www.regulations.gov/.* Although listed, 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. With the exception of such material, publicly available docket materials are available electronically in *Regulations.gov*.

Instructions. Direct your comments to Docket ID No. EPA–HQ–OAR–2002–0083. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *https://www.regulations.gov/,* including any personal information provided, unless the comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit electronically to *https://www.regulations.gov* any information that you consider to be CBI or other information whose disclosure is restricted by statute. This type of information should be submitted as discussed below.

The EPA may publish any comment received to its public docket. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the Web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

The *https://www.regulations.gov/* website allows you to submit your comment anonymously, which means the EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to the EPA without going through *https://www.regulations.gov/,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, the EPA recommends that you include your name and other contact information in the body of your comment and with any digital storage media you submit. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should not include special characters or any form of encryption and be free of any defects or viruses. For additional information about the EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Submitting CBI. Do not submit information containing CBI to the EPA through *https://www.regulations.gov/.* Clearly mark the part or all of the information that you claim to be CBI. For CBI information on any digital storage media that you mail to the EPA, note the docket ID, mark the outside of the digital storage media as CBI and identify electronically within the digital storage media the specific information that is claimed as CBI. In addition to one complete version of the comments that includes information claimed as CBI, you must submit a copy of the comments that does not contain the information claimed as CBI directly to the public docket through the procedures outlined in the *Instructions* section of this document. If you submit any digital storage media that does not contain CBI, mark the outside of the digital storage media clearly that it does not contain CBI and note the docket ID. Information not marked as CBI will be included in the public docket and the EPA's electronic public docket without prior notice. Information marked as CBI will not be disclosed except in accordance with procedures set forth in 40 CFR (Code of Federal Regulations) part 2.

Our preferred method to receive CBI is for it to be transmitted electronically using email attachments, File Transfer Protocol (FTP), or other online file sharing services (*e.g.,* Dropbox, OneDrive, Google Drive). Electronic

submissions must be transmitted directly to the OAQPS CBI Office at the email address *oaqpscbi@epa.gov,* and as described above, should include clear CBI markings and note the docket ID. If assistance is needed with submitting large electronic files that exceed the file size limit for email attachments, and if you do not have your own file sharing service, please email *oaqpscbi@epa.gov* to request a file transfer link. If sending CBI information through the postal service, please send it to the following address: OAQPS Document Control Officer (C404–02), OAQPS, U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711, Attention Docket ID No. EPA–HQ–OAR–2002–0083. The mailed CBI material should be double wrapped and clearly marked. Any CBI markings should not show through the outer envelope.

Preamble acronyms and abbreviations. Throughout this preamble the use of ''we,'' ''us,'' or ''our'' is intended to refer to the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

1-BP 1-bromopropane
ACI activated carbon injection
BF blast furnace
BOPF basic oxygen process furnace
BTF Beyond-the-Floor
CAA Clean Air Act
CBI Confidential Business Information
COS Carbonyl Sulfide
CFR Code of Federal Regulations
D/F dioxins and furans
EAV equivalent annualized value
EJ environmental justice
EPA Environmental Protection Agency
FR Federal Register
HAP hazardous air pollutant(s)
HCl hydrochloric acid
HF hydrogen fluoride
HMTDS hot metal transfer, desulfurization, and skimming
ICR Information Collection Request
km kilometer
MACT maximum achievable control technology
NESHAP national emission standards for hazardous air pollutants
NTTAA National Technology Transfer and Advancement Act
OAQPS Office of Air Quality Planning and Standards
OMB Office of Management and Budget
PAH polycyclic aromatic hydrocarbons
PM particulate matter
PRA Paperwork Reduction Act
PV present value
RFA Regulatory Flexibility Act
RTR residual risk and technology review
THC total hydrocarbon
TEQ toxic equivalents
tpy tons per year
UFIP unmeasured fugitive and intermittent particulate
UMRA Unfunded Mandates Reform Act
UPL upper prediction limit
VCS voluntary consensus standards
VE visible emissions
VOC volatile organic compound
WP work practice

Organization of this document. The information in this preamble is organized as follows below. Section III of this preamble presents a summary of the analytical procedures and decision-making process. Section IV of this preamble describes the majority of the Agency's analytical results, proposed decisions and the rationale for the actions proposed in this action. Other sections include discussion of costs and impacts and the applicable executive orders, and other relevant topics, as outlined in the following table of contents.

Table of Contents

I. General Information
A. Executive Summary
B. Does this action apply to me?
C. Where can I get a copy of this document and other related information?
II. Background
A. What is the statutory authority for this action?
B. What is this source category and how does the current NESHAP regulate its HAP emissions?
C. What data collection activities were conducted to support this action?
D. What other relevant background information and data are available?
III. Analytical Procedures and Decision-Making
A. How do we perform the technology review?
B. How do we develop and calculate CAA section 112(d)(2) and (3) standards?
IV. Analytical Results and Proposed Decisions
A. Proposed Standards To Address Five Unregulated UFIP Sources for Both New and Existing Sources
B. Reconsideration of BF Casthouse and BOPF Shop Standards for Currently Regulated Fugitive Sources Under CAA 112(D)(6) Technology Review for Both New and Existing Sources
C. Results of Fenceline Monitoring Data Analyses
D. What are the proposed decisions based on our fenceline monitoring data analysis, and what is the rationale for those decisions?
E. Proposed Standards To Address Unregulated Point Sources for Both New And Existing Sources
F. Reconsideration of Standards for D/F and PAH for Sinter Plants Under CAA Section 112 (D)(6) Technology Review for Both New and Existing Sources
G. Adding 1-Bromopropane to List of HAP
H. What compliance dates are we proposing?
V. Summary of Cost, Environmental, and Economic Impacts
A. What are the affected sources?
B. What are the air quality impacts?
C. What are the cost impacts?
D. What are the economic impacts?
E. What are the benefits? F. What analysis of environmental justice did we conduct?
VI. Request for Comments
VII. Statutory and Executive Order Reviews
A. Executive Order 12866: Regulatory Planning and 13563 Improving Regulation and Regulatory Review
B. Paperwork Reduction Act *(PRA)*
C. Regulatory Flexibility Act *(RFA)*
D. Unfunded Mandates Reform Act *(UMRA)*
E. Executive Order 13132: Federalism
F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use
I. National Technology Transfer and Advancement Act *(NTTAA) and 1 CFR Part 51*
J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

I. General Information

A. Executive Summary

1. Purpose of the Regulatory Action

The EPA set maximum achievable control technology (MACT) standards for the Integrated Iron and Steel Manufacturing Facilities major source category in 2003 (68 FR 27645) under 40 CFR part 63, subpart FFFFF and completed a residual risk and technology review final rule in July 2020 (85 FR 42074). The purpose of this proposed rule is to (1) fulfill the EPA's statutory obligations pursuant to CAA section 112(d)(6) and the U.S. Court of Appeals for the D.C. Circuit's interpretation of that statute in *Louisiana Environmental Action Network* v. *EPA,* 955 F.3d 1088 (D.C. Cir. 2020) (''*LEAN*''), and (2) improve the emissions standards for this source category based on new information regarding developments in practices, processes and control technologies.

2. Summary of the Major Provisions of the Regulatory Action

To comply with CAA section 112, we are proposing (1) new emissions limits based on MACT for five currently unregulated HAP (COS, CS_2, Hg, HCl, and HF) from the sinter plants located at integrated iron and steel manufacturing facilities and (2) new MACT standards, in the form of opacity limits and work practice (WP)

standards, for five unregulated sources of UFIP emissions: Unplanned Bleeder Valve Openings, Planned Bleeder Valve Openings, Slag Pits, Beaching, and Bell Leaks. In this context, opacity is a measure of the amount of light that is blocked or absorbed by an air pollution plume. The components of air pollution that block or absorb light are primarily particulate matter (PM), or PM. An opacity level of 0 percent means that any plumes of air pollution do not block or absorb light and are fully transparent (i.e., no visble emissions). On the other hand, an opacity of 100 percent would mean that the plume is quite dense and blocks all light (i.e., the trained observer or special camera can not see any background behind the plume). Observers are trained and certified using smoke generators which produce known opacity levels, and periodic recertification is required every six months. More details regarding the EPA approved method for opacity readings by a trained observer are available at the following website: *https://www.epa.gov/emc/method-9-visual-opacity.* Alternatively, opacity can be observed with special cameras following a specific method (known as the digital camera opacity technique (DCOT), 40 CFR 63.7823), and those images interpreted by trained individuals. For the Integrated Iron and Steel Manufacturing (and a number of other metals processing and production sectors), we know that a significant portion of the emitted PM is comprised HAP metals (such as arsenic, lead, manganese, chromium) that are primarily emitted in particulate form. Therefore, for this industry as well as several other industries, PM serves as a surrogate for particulate HAP metals.

We are also proposing new emissions limits for three unregulated pollutants for BF stoves and BOPFs: total hydrocarbons (THC), HCl, and D/F, and for two unregulated pollutants for BFs: THC and HCl. In this action, pursuant to CAA section 112(d)(6), we are also proposing to: (1) Revise the current BOPF shop fugitive 20 percent opacity limit to a 5 percent opacity limit and require certain work practices; (2) revise the current BF casthouse fugitive 20 percent opacity limit to a 5 percent opacity limit; (3) add a fenceline monitoring requirement to help ensure the work practices and opacity limits are achieving the anticipated reductions; and (4) revise standards for D/F and PAHs from sinter plants to reflect the performance of current control devices.

3. Costs and Benefits

To meet the requirements of E.O. 12866, the EPA projected the emissions reductions, costs, and benefits that may result from the proposed rule. These results are presented in detail in the regulatory impact analysis (RIA) accompanying this proposal developed in response to E.O. 12866. The proposed rule is significant under E.O. 12866 Section 3(f)(1), as amended by E.O. 14094 due to the monetized benefits of fine particulate matter ($PM_{2.5}$) reductions likely to result from the UFIP emissions standards included in the proposed rule. The RIA, which is available in the docket for this action, focuses on the elements of the proposed rule that are likely to result in quantifiable cost or emissions changes compared to a baseline without the proposed regulatory requirements. We estimated the cost, emissions, and benefit impacts for the 2025 to 2034 period, discounted to 2023. We show the present value (PV) and equivalent annualized value (EAV) of costs, benefits, and net benefits of this action in 2022 dollars. The EAV represents a flow of constant annual values that would yield a sum equivalent to the PV. The EAV represents the value of a typical cost or benefit for each year of the analysis, consistent with the estimate of the PV, in contrast to year-specific estimates.

The initial analysis year in the RIA is 2025 because we assume that will be the first year of full implementation of the rule. We are proposing that facilities will have 1 year to demonstrate compliance with the relevant standards following promulgation. This analysis assumes full compliance with the proposed standards will occur in late 2024 given the expected promulgation of this rule in late 2023. Therefore, the first full year of impacts will occur in 2025. The final analysis year is 2034, which allows us to provide 10 years of projected impacts after the rule takes effect.

The cost analysis presented in the RIA reflects a nationwide engineering analysis of compliance cost and emissions reductions. Impacts are calculated by setting parameters on how and when affected facilities are assumed to respond to a particular regulatory regime, calculating estimated cost and emissions impact estimates for each facility, differencing from the baseline scenario, and then summing to the desired level of aggregation.

The EPA expects health benefits due to the emissions reductions projected from the rule. We expect that hazardous air pollutant (HAP) emission reductions will improve health and welfare associated with reduced exposure for those affected by these emissions. In addition, the EPA expects that $PM_{2.5}$ emission reductions that will occur concurrent with the reductions in HAP emissions will improve air quality and are likely to improve health and welfare associated with exposure to $PM_{2.5}$ and HAP. For the RIA, the EPA monetized benefits associated with premature mortality and morbidity from reduced exposure to $PM_{2.5}$. Discussion of both the monetized and non-monetized benefits can be found in Chapter 4 of the RIA.

Table 1 presents the emission changes and the PV and EAV of the projected monetized benefits, compliance costs, and net benefits over the 2025 to 2034 period under the rule. All discounting of impacts presented uses social discount rates of 3 and 7 percent.

TABLE 1—MONETIZED BENEFITS, COSTS, NET BENEFITS, AND EMISSIONS REDUCTIONS OF THE PROPOSED NESHAP SUBPART FFFFF AMENDMENTS, 2025 THROUGH 2034 [a]

[Dollar estimates in millions of 2022 dollars, discounted to 2023]

	3 Percent discount rate		7 Percent discount rate	
	PV	EAV	PV	EAV
Benefits [b]	$2,300 and $2,400	$260 and $280	$1,700 and $1,700	$220 and $230.
Compliance Costs	$39	$4.6	$32	$4.6.
Net Benefits	$2,300 and $2,400	$260 and $280	$1,700 and $1,700	$220 and $230.
Emissions Reductions (short tons)	2025–2034 Total			
HAP	790			
PM	23,000			

TABLE 1—MONETIZED BENEFITS, COSTS, NET BENEFITS, AND EMISSIONS REDUCTIONS OF THE PROPOSED NESHAP SUBPART FFFFF AMENDMENTS, 2025 THROUGH 2034 [a]—Continued

[Dollar estimates in millions of 2022 dollars, discounted to 2023]

	3 Percent discount rate		7 Percent discount rate	
	PV	EAV	PV	EAV
$PM_{2.5}$	5,600			
Non-monetized Benefits in this Table	HAP benefits from reducing 790 short tons of HAP from 2025–2034. Non-health benefits from reducing 23,000 tons of PM, of which 5,600 tons is $PM_{2.5}$, from 2025–2034. Visibility benefits. Reduced ecosystem/vegetation effects.			

[a] Totals may not sum due to independent rounding. Numbers rounded to two significant digits unless otherwise noted.

[b] Monetized benefits include health benefits associated with reductions in $PM_{2.5}$ emissions. The monetized health benefits are quantified using two alternative concentration-response relationships from the Di et al. (2016) and Turner et al. (2017) studies and presented at real discount rates of 3 and 7 percent. The two benefits estimates are separated by the word ''and'' to signify that they are two separate estimates. Benefits from HAP reductions remain unmonetized and are thus not reflected in the table.

B. Does this action apply to me?

Table 2 of this preamble lists the NESHAP and associated regulated industrial source categories that are the subject of this proposal. Table 2 is not intended to be exhaustive, but rather provides a guide for readers regarding the entities that this proposed action is likely to affect. The proposed standards, once promulgated, will be directly applicable to the affected sources. Federal, State, local, and Tribal government entities would not be affected by this proposed action. As defined in the *Initial List of Categories of Sources Under Section 112(c)(1) of the Clean Air Act Amendments of 1990* (see 57 FR 31576, July 16, 1992) and *Documentation for Developing the Initial Source Category List, Final Report* (see EPA–450/3–91–030, July 1992), the Integrated Iron and Steel Manufacturing Facilities source category is any facility engaged in producing steel from iron ore. Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a hot gas. The steel production process includes BOPFs.

TABLE 2—NESHAP AND INDUSTRIAL SOURCE CATEGORIES AFFECTED BY THIS PROPOSAL

Source category	NESHAP	NAICS code [1]
Integrated Iron and Steel Manufacturing Facilities	40 CFR part 63, subpart FFFFF	331110

[1] North American Industry Classification System.

C. Where can I get a copy of this document and other related information?

In addition to being available in the docket, an electronic copy of this action is available on the internet. Following signature by the EPA Administrator, the EPA will post a copy of this proposed action at *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission-standards.* Following publication in the **Federal Register**, the EPA will post the **Federal Register** version of the proposal and key technical documents at this same website.

A memorandum showing the rule edits that would be necessary to incorporate the changes to 40 CFR part 63, subpart FFFFF proposed in this action is available in the docket (Docket ID No. EPA–HQ–OAR–2002–0083). The EPA also will post a copy of this document to *https://www.epa.gov/stationary-sources-air-pollution/integrated-iron-and-steel-manufacturing-national-emission-standards.*

II. Background

A. What is the statutory authority for this action?

This action proposes to amend the National Emission Standards for Hazardous Air Pollutants (NESHAP) for the Integrated Iron and Steel Manufacturing Facilities source category.

The statutory authority for this action is provided by section 112 of the CAA, as amended (42 U.S.C. 7401, *et seq.*). In the first stage of the CAA section 112 standard-setting process, the EPA promulgates technology-based standards under CAA section 112(d) for categories of sources identified as emitting one or more of the HAP listed in CAA section 112(b). Sources of HAP emissions are either major sources or area sources, and CAA section 112 establishes different requirements for major source standards and area source standards. ''Major sources'' are those that emit or have the potential to emit 10 tons per year (tpy) or more of a single HAP or 25 tpy or more of any combination of HAP. All other sources are ''area sources.'' For major sources, CAA section 112(d)(2) provides that the technology-based NESHAP must reflect the maximum degree of emission reductions of HAP achievable (after considering cost, energy requirements, and non-air quality health and environmental impacts). These standards are commonly referred to as MACT standards. CAA section 112(d)(3) also establishes a minimum control level for MACT standards, known as the MACT ''floor.'' In certain instances, as provided in CAA section 112(h), the EPA may set work practice standards in lieu of numerical emission standards. The EPA must also consider control options that are more stringent than the floor. Standards more stringent than the floor are commonly referred to as ''beyond-the-floor'' (BTF) standards.

CAA section 112(d)(6) requires the EPA to review standards promulgated

under CAA section 112 and revise them ''as necessary (taking into account developments in practices, processes, and control technologies)'' no less often than every eight years. While conducting this review, which we call the ''technology review,'' the EPA is not required to recalculate the MACT floors that were established during earlier rulemakings. *Nat. Resources Def. Council (NRDC)* v. *EPA,* 529 F.3d 1077, 1084 (D.C. Cir. 2008); *Ass'n of Battery Recyclers, Inc.* v. *EPA,* 716 F.3d 667 (D.C. Cir. 2013). The EPA may consider cost in deciding whether to revise the standards pursuant to CAA section 112(d)(6).

CAA section 112(f) requires the EPA to determine whether promulgation of additional standards is needed to provide an ample margin of safety to protect public health or to prevent an adverse environmental effect. This review is known as the ''residual risk review,'' and it must occur within eight years after promulgation of the standards. When EPA conducts the ''technology review'' together with the ''residual risk review,'' the combined review is known as a ''risk and technology review'' or ''RTR.''

The EPA initially promulgated the Integrated Iron and Steel Manufacturing Facilities NESHAP on May 20, 2003 (68 FR 27645), under title 40, part 63, subpart FFFFF (the NESHAP). The rule was amended on July 13, 2006 (71 FR 39579). The amendments added a new compliance option, revised emission limitations, reduced the frequency of repeat performance tests for certain emission units, added corrective action requirements, and clarified monitoring, recordkeeping, and reporting requirements.

In 2015, a coalition of environmental advocacy groups filed a lawsuit to compel the EPA to fulfill its statutory duty to conduct the CAA sections 112(d) and 112(f)(2) reviews of 21 NESHAPs, including Integrated Iron & Steel Manufacturing Facilities. As a result of that litigation, the EPA was required by court order to complete the RTR for the Integrated Iron and Steel Manufacturing Facilities source category by May 5, 2020. *California Communities Against Toxics* v. *Wheeler,* No. 1:15–cv–00512, Order (D.D.C. March 13, 2017, as modified February 20, 2020). The resulting residual risk and technology review (RTR) conducted for the Integrated Iron and Steel Manufacturing Facilities NESHAP was signed on May 4, 2020. 85 FR 42074 (July 13, 2020).

In an April 2020 decision by the U.S. Court of Appeals for the District of Columbia Circuit, the court held that the EPA has an obligation to address unregulated HAP emissions from a source category when the Agency conducts the eight-year technology review required by CAA section 112(d)(6). *LEAN,* 955 F.3d at 1098–99. The parties in the *California Communities Against Toxics* case therefore filed a joint motion for an extension of the deadline to allow the EPA to revise the 2020 final rule to comply with the *LEAN* opinion. The court granted the motion, setting a new deadline for this rule of October 26, 2023. *California Communities Against Toxics,* Order (D.D.C. April 14, 2021).

And finally, in September 2021, industry and environmental advocacy groups filed petitions for review of the 2020 final rule, and these petitions have been consolidated. *American Iron and Steel Inst., et al.* v. *EPA,* No. 20–1354 (D.C. Cir.); *Clean Air Council, et al.* v. *EPA,* No. 20–1355 (D.C. Cir.). The consolidated case is in abeyance pending this rulemaking. *American Iron and Steel Inst.,* No. 20–1354 (consol.), Order, Dec. 7, 2022.

In light of this litigation history, today's proposed rule includes: (1) Proposed new standards to address currently unregulated emissions of HAP from the Integrated Iron and Steel Manufacturing Facilities source category pursuant to the *LEAN* decision and CAA sections 112(d)(2) and (3) and 112(h) and, (2) proposed revised standards for a few currently regulated HAP and fenceline monitoring requirements pursuant to the CAA section 112(d)(6) technology review.

B. What is this source category and how does the current NESHAP regulate its HAP emissions?

As described above, the Integrated Iron and Steel Manufacturing Facilities source category includes any facility engaged in producing steel from refined iron ore (also known as taconite pellets). These facilities first produce iron from iron ore taconite pellets, sinter, coke, and other raw materials using blast furnaces (BFs), then produce steel from the hot liquid iron from the blast furnaces, along with coke, lime, alloys, steel scrap, and other raw materials using basic oxygen process furnaces (BOPFs). Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a very hot gas. The steel production process includes BOPFs and ladle metallurgy operations. Currently there are eight operating facilities in this source category.

The main sources of HAP emissions from integrated iron and steel manufacturing are the BF; BF stove; BOPF; hot metal transfer, desulfurization, and skimming (HMTDS) operations; ladle metallurgy operations; sinter plant windbox; sinter plant discharge end; and sinter cooler. All nine facilities have BFs, BF stoves, BOPFs, HMTDS operations, and ladle metallurgy operations. However, only three facilities have sinter plants.

The following are descriptions of the BF, BOPF, and sinter plants:

- The BF is a key integrated iron and steel process unit where molten iron is produced from raw materials such as iron ore, lime, sinter, coal and coke.
- The BOPF is a key integrated iron and steel process unit where steel is made from molten iron, scrap steel, lime, dolomite, coal, coke, and alloys.
- Sinter is derived from material formed in the bottom of the blast furnace, composed of oily scale, blast furnace sludge, and coke breeze, along with tarry material and oil absorbed from the sump in which the sinter is recovered. The sinter plant processes the waste that would otherwise be landfilled so that iron and other valuable materials can be re-used in the blast furnace. Only three sources covered by the Integrated Iron and Steel Manufacturing Facility category have sinter plants, down from nine facilities with sinter plants in 2003.

In addition to point sources, the EPA identified seven UFIP emission sources for this source category, including BF bleeder valve unplanned openings BF bleeder valve planned openings, BF bell leaks, BF casthouse fugitives, BF iron beaching, BF and BOPF slag handling and storage operations, and BOPF shop fugitives. Some of these UFIP sources are also referred to as ''fugitive'' or ''nonpoint'' sources of emissions. These UFIP emission sources were identified by observation of visible plumes by EPA regional staff during onsite inspections and were subsequently investigated to determine the causes and any possible methods for reductions. These inspections were documented in numerous reports and photographs between 2008 and the present.[1] The NESHAP currently regulates two of these sources—BF casthouse fugitives

[1] *E.g.,* communications between B. Dickens and P. Miller, U.S. EPA Region V, Chicago, IL, with D. L. Jones, U.S. EPA, Office of Air Quality Planning and Standards, Office of Air and Radiation, 2015–2018. See also *Ample Margin of Safety for Nonpoint Sources in the II&S Industry,* available in the docket to this rule.

and BOPF shop fugitives—with opacity limits.

The following are descriptions of the seven UFIP sources. More details can be found in the technical memoranda discussed below in Section II.D.

- The BF is a key integrated iron and steel process unit where molten iron is produced from raw materials such as iron ore, lime, sinter, coal and coke.
- The BOPF is a key integrated iron and steel process unit where steel is made from molten iron, scrap steel, lime, dolomite, coal, coke, and alloys.
- Sinter is derived from material formed in the bottom of the blast furnace, composed of oily scale, blast furnace sludge, and coke breeze, along with tarry material and oil absorbed from the sump in which the sinter is recovered. The sinter plant processes the waste that would otherwise be landfilled so that iron and other valuable materials can be re-used in the blast furnace. Only three sources covered by the Integrated Iron and Steel Manufacturing Facility category have sinter plants, down from nine facilities with sinter plants in 2003.
- The BOPF shop is the structure that houses the entire BOPF and auxiliary activities, such as hot iron transfer, skimming, and desulfurization of the iron and ladle metallurgy operations, which generate fugitive emissions.
- The BF casthouse is the structure that houses the lower portion of the BF and encloses the tapping operation and the iron and slag transport operations, which generate fugitive emissions.
- The bleeder valve is a device at the top of the BF that, when open, relieves BF internal pressure to the ambient air. The valve can operate as both a self-actuating safety device to relieve excess pressure and as an operator-initiated instrument for process control. A bleeder valve opening means any opening of the BF bleeder valve, which allows gas and/or PM to flow past the sealing seat. Multiple openings and closings of a bleeder valve that occur within a 30-minute period could be considered a single bleeder valve opening. There are two types of openings, planned and unplanned.
- A planned bleeder valve opening means an opening that is initiated by an operator as part of a furnace startup, shutdown, or temporary idling for maintenance action. Operators can prepare the furnace for planned openings to minimize or eliminate emissions from the bleeder valves.
- An unplanned bleeder valve opening means an opening that is not planned and is caused by excess pressure within the furnace. The pressure buildup can occur when raw materials do not descend smoothly after being charged at the top of the BF and accumulate in large masses within the furnace. When the large masses finally dislodge (slip) due to their weight, a pressure surge results.
- Slag is a by-product containing impurities that is released from the BF or BOPF along with molten iron when the BF or BOPF is tapped from the bottom of the furnace. The slag is less dense than iron and, therefore, floats on top of the iron. Slag is removed by skimmers and then transported to open pits to cool to enable later removal. Usually there is one slag pit for every BF or BOPF.
- Iron beaching occurs when iron from BF cannot be charged to the BOPF because of problems in steelmaking units; the hot molten iron from the BF is placed onto the ground, in some cases within a three-sided structure.
- The BF bells are part of the charging system on top of the furnace that allows for materials to be loaded into the furnace or next bell (as in the case of small bells) without letting BF gas escape. It is a two-bell system, where a smaller bell is above a larger bell. These bells need to have a tight seal onto the blast furnace when not in use for charging so that BF gas and uncontrolled emissions do not escape to the atmosphere. Over time, the surfaces that seal the bells wear down and need to be repaired (for small bells) or replaced (for large bells). If these seals are not repaired or replaced in a timely manner, emissions of HAP and PM can increase significantly.

In the 2020 final rule, the Agency found that risks due to emissions of air toxics from this source category were acceptable and concluded that the NESHAP provided an ample margin of safety to protect public health. Under the technology review in the 2020 RTR, EPA found no developments in practices, processes, or control technologies that necessitated revision of the standards at that time. However, in response to a 2004 administrative petition for reconsideration, the 2020 final rule promulgated a new MACT emissions limit for mercury (0.00026 lbs mercury/ton scrap metal) with two compliance options: (1) Conduct annual compliance tests (to demonstrate compliance with the MACT limit) or (2) confirm that the facility obtains their auto scrap from suppliers that participate in the National Vehicle Mercury Switch Recovery Program (NVMRP) or another approved mercury switch removal program or that the facility only uses scrap that does not contain mercury switches. We also removed exemptions for periods of startup, shutdown, and malfunction (SSM) consistent with a 2008 court decision and clarified that the emissions standards apply at all times; added electronic reporting of performance test results and compliance reports; and made minor corrections and clarifications for a few other rule provisions. All documents used to develop the previous 2003, 2006, and 2020 final rules can be found in either the legacy docket, A–2000–44, or the electronic docket, EPA–HQ–OAR–2002–0083.

The current NESHAP includes emissions limits for particulate matter (PM) and opacity standards (both of which are surrogates for non-mercury PM HAP metals) for furnaces and sinter plants. To support the continued use of PM as a surrogate for certain non-mercury HAP metals, we considered the holding in *National Lime* v. *EPA,* 233 F.3d 625 (D.C. Cir. 2000). In considering whether the EPA may use PM, a criteria pollutant, as a surrogate for metal HAP, the D.C. Circuit stated that the EPA ''may use a surrogate to regulate hazardous pollutants if it is 'reasonable' to do so,'' *id.* at 637, and laid out criteria for determining whether the use of PM as a surrogate for non-mercury metal HAP was reasonable. The court found that PM is a reasonable surrogate for HAP if: (1) ''HAP metals are invariably present'' in the source's PM,'' *id.;* (2) the ''source's PM control technology indiscriminately captures HAP metals along with other particulates,'' *id.* at 639; and (3) ''PM control is the only means by which facilities 'achieve' reductions in HAP metal emissions,'' *id.* If these criteria are satisfied and the PM emission standards reflect what the best sources achieve in compliance with CAA section 112(d)(3), ''EPA is under no obligation to achieve a particular numerical reduction in HAP metal emissions.'' *Id.* The EPA has established and promulgated PM limits as a surrogate for particulate HAP metals successfully in several previous NESHAP including Ferroalloys Production (80 FR 37366, June 30, 2015), Taconite Iron Ore Processing NESHAP (68 FR 61868), and Primary Copper Smelting NESHAP (67 FR 40478, June 12, 2002).

The NESHAP also includes an operating limit for the oil content of the sinter plant feedstock or, as an alternative, an emissions limit for volatile organic compounds (VOC) for the sinter plant windbox exhaust stream. The oil limit, and the alternative VOC limit, serve as surrogates for all organic HAP. Moreover, the NESHAP includes an emissions limit for mercury emissions from the BOPF Group, which

is the collection of BOPF shop steelmaking operating units and their control devices including the BOPF primary emission control system, BOPF secondary control system, ladle metallurgy units, and hot metal transfer, desulfurization and slag skimming units.

C. What data collection activities were conducted to support this action?

The EPA issued a CAA section 114 information request in January 2022, including a facility questionnaire and source testing request, to both parent companies in this source category, resulting in information for all eight operating facilities. The questionnaire requested information in the following categories: general facility information, process unit tables, and UFIP emission information. Facility responses provided information regarding which UFIP work practices are currently being utilized or have been tried in the past, and any benefits, drawbacks, or complications of each one. They also provided information about the frequencies of some of their intermittent emissions, such as planned and unplanned bleeder valve openings. The compilation of the facility responses can be found in the docket for this proposed rulemaking (EPA–HQ–OAR–2002–0083). The information we received on UFIP emissions helped us develop the standards in this proposed rule. The EPA requested source testing for HAP metals and hydrogen fluoride (HF) at the sinter plant windbox control device and opacity data for the fugitive and intermittent particulate sources. In addition, the EPA requested fenceline monitoring for lead, arsenic and chromium at four facilities.

In September 2022, the EPA issued a supplemental CAA section 114 information request for additional source testing at one facility for each parent company. From one facility, we requested source testing for HCl and total hydrocarbons for the BF stove, BF casthouse, and the BOPF primary control device, as well as source testing for D/F from the BF stove and the BOPF primary control device. From the other facility, we requested source testing for HCl and D/F from the BOPF primary control device, as well as source testing for D/F at the outlet of the boiler from the BF stove. One additional facility voluntarily submitted test reports for HCl and THC for the BF stove and BF casthouse, as well as THC source testing for the BOPF primary control device. These data were gathered to supplement data we already had from the 2020 RTR rule development, which is described in the 2019 RTR proposed on August 16, 2019 (84 FR 42704), and in technical support documents cited in that notice. The compilation of source testing results can be found in the docket for this action (EPA–HQ–OAR–2002–0083).

D. What other relevant background information and data are available?

The EPA used several resources, including industry consultation, AP–42 Compilation of Air Pollutant Emission Factors, Fifth Edition, dated January 15, 1995, as amended with Supplements and Updates, EPA studies, and other published technical documents to estimate emissions for the UFIP sources. The seven UFIP sources and development of emissions estimates for these sources at an example facility are described in detail in three technical memoranda. The first, *Ample Margin of Safety for Nonpoint Sources in the II&S Industry May 1, 2019,* available in the docket for this rule (EPA–HQ–OAR–2002–0083–0953), describes the seven UFIP sources, work practices that can help reduce or minimize HAP and PM emissions, estimated costs of these work practices, and estimated risks before and after implementation of work practices based on the 2019–2020 RTR rulemaking analyses. The second, *Development of Emissions Estimates for Fugitive or Intermittent HAP Emission Sources for an Example Integrated Iron and Steel Manufacturing Facility for Input to the RTR Risk Assessment 5/1/2020,* also available in the docket (EPA–HQ–OAR–2002–0083–1094), describes the following: (1) The development of emissions estimates for UFIP from processes where emissions from UFIP are thought to occur; (2) estimates of PM emissions from these processes; (3) HAP-to-PM ratios used to estimate HAP emissions from the PM emissions estimates; and (4) the resulting HAP emissions estimated. These two memoranda were developed to support the 2019 proposed RTR rule and the 2020 final RTR rule.

We further developed updated estimates of HAP, PM, and $PM_{2.5}$ emissions from the UFIP at all other operating Integrated Iron and Steel Manufacturing Facility sources, which are described in the third and most recent 2023 memorandum, *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* available in the docket for this action.

Also, regarding the proposed requirements for the UFIP sources (described below), industry representatives provided additional information including suggested opacity limits and work practices (and suggested regulatory text).[2] Furthermore, we received additional data and information from industry in April, but we were unable to review and analyze this information for this proposal given the timing of its submission.[3] We solicit comments on the information and suggestions that industry provided including whether EPA should adopt some or all of these suggestions and a thorough explanation as to why, or why not.

III. Analytical Procedures and Decision-Making

A. How do we perform the technology review?

Our technology review primarily focuses on the identification and evaluation of developments in practices, processes, and control technologies that have occurred since the MACT standards were promulgated. Where we identify such developments, we analyze their technical feasibility, estimated costs, energy implications, and non-air health and environmental impacts. The EPA also considers the emission reductions associated with applying each development. This analysis informs our decision of whether it is ''necessary'' to revise the emissions standards. In addition, the Agency considers the appropriateness of applying controls to new sources versus retrofitting existing sources. For this exercise, the EPA considers any of the following to be a ''development'':

- Any add-on control technology or other equipment that was not identified and considered during development of the original MACT standards;
- Any improvements to the add-on control technology or other equipment that was identified and considered during development of the original MACT standards that could result in additional emissions reductions;
- Any work practice or operational procedure that was not identified or considered during development of the original MACT standards;
- Any process change or pollution prevention alternative that could be broadly applied to the industry and that was not identified or considered during development of the original MACT standards; and

[2] See February 22, 2023 email from Paul Balserak, American Iron and Steel Institute (AISI), and the attachment to that email, ''II&S DRAFT PROPOSED RULE UFIP LANGUAGE,'' available in the docket for this action.

[3] See April 12, 2023 email from Paul Balserak, AISI, and two attachments, ''PRELIMINARY FEEDBACK ON POTENTIAL STANDARDS FOR THE INTEGRATED IRON AND STEEL MANUFACTURING NESHAP'' & ''Attachment A to Supp to Jan and Feb Submittals,'' available in the docket for this action.

• Any significant changes in the cost (including cost effectiveness) of applying controls, including controls the EPA considered during the development of the original MACT standards.

In addition to reviewing the practices, processes, and control technologies that were considered at the time the EPA originally developed the NESHAP, we review a variety of data sources in our investigation of potential practices, processes, or controls to consider. The EPA also reviews the NESHAP and the available data to determine whether there are any unregulated emissions of HAP within the source category and evaluates the data for use in developing new emission standards. See sections II.C and II.D of this preamble for information on the specific data sources that were reviewed as part of the technology review.

B. How do we develop and calculate CAA section 112(d)(2) and (3) standards?

The MACT floor limits for relevant HAP are calculated based on the average performance of the best-performing five units in each category or subcategory and on a consideration of these units' variability. The MACT floor for new sources is based on the single best-performing source, with a similar consideration of that source's variability. The MACT floor for new sources cannot be less stringent than the emissions performance that is achieved in practice by the best-controlled similar source. To account for variability in the operation and emissions, we calculated the MACT floor emissions limits for this source category using the 99 percent Upper Predictive Limit (UPL) using the available stack emissions test results. We note that the MACT floor limits for new units are based on a limited data set.[4]

The UPL approach addresses variability of emissions test data from the best-performing source or sources in setting MACT standards. The UPL also accounts for uncertainty associated with emission values in a dataset, which can be influenced by components such as the number of samples available for developing MACT standards and the number of samples that will be collected to assess compliance with the emission limit. The UPL approach has been used in many environmental science applications. As explained in more detail in the UPL Memo cited above, the EPA uses the UPL approach to reasonably estimate the emissions performance of the best-performing source or sources to establish MACT floor standards when the EPA has emissions test data that allow for such calculations.

After the MACT floor limits are developed, the EPA also evaluates potential beyond-the-floor (BTF) options (*i.e.,* more stringent options) to determine whether there are cost-effective appropriate standards that can achieve additional reductions that should be proposed instead of the MACT floor standards.

IV. Analytical Results and Proposed Decisions

A. Proposed Standards To Address Five Unregulated UFIP Sources for Both New and Existing Sources

1. BF Unplanned Bleeder Valve Openings

Sometimes raw material within the BF builds up, fails to descend smoothly, and falls or slips. Sometimes these slips create a pressure surge that is relieved, along with excess pollutant emissions (*e.g.,* PM with HAP metals), out of bleeder valves that are positioned about 100 feet above the casthouse. If the slip results in the valve opening, we call this an ''unplanned opening.'' Unplanned openings can last between a few seconds and ten minutes, and occur between 0 to 7 times per month, and fewer slips and fewer unplanned openings occur with better screening of raw material and more attentive furnace operation to enable early action to avoid unplanned openings. Based on the data we received through the section 114 requests, the average number of unplanned openings of the best performing five furnaces in the source category is 5 unplanned openings per year. Therefore, we estimate that the MACT floor level of performance is 5 unplanned openings per year.

All slips are preceded by raw material hanging in the furnace, creating a bridge. It is our understanding that because furnaces have level indicators, furnace operators should know when conditions for a slip are forming, and if they are forming, operators should be able to take action to induce a small slip that can avoid a larger slip that ultimately causes an unplanned bleeder valve opening. It is our understanding that hanging of raw material can be avoided or significantly reduced by screening fine particulates from the raw material. Therefore, unplanned openings should be limited to a significant extent by operators monitoring the furnace and taking actions when certain parameter readings indicate a slip may occur.

We estimate that about 2.1 tpy of HAP metals are emitted from the Integrated Iron and Steel source category due to these unplanned openings. Because unplanned openings are variable, only last for up to 10 minutes, and due to the structure of the bleeder valves, it is not technically or economically feasible to reliably measure emissions from unplanned openings. Therefore, based on our evaluation of available information, pursuant to CAA section 112(d)(2) and (3) and CAA section 112(h), we are proposing work practice standards that would require facilities to do the following: (1) Install and operate devices (*e.g.,* stockline monitors) to continuously measure/monitor material levels in the furnace, at a minimum of three locations, using alarms to inform operators of static conditions that indicate a slip may occur, and therefore, in turn, alert them that there is a need to take action to prevent the unplanned openings from occurring; (2) install and operate instruments such as a thermocouple and transducer on the furnace to monitor temperature and pressure to help determine when a slip may occur; (3) install a screen to remove fine particulates from raw materials to ensure only properly-sized raw materials are charged into the BF; and (4) develop, and submit to the EPA for approval, a plan that explains how the facility will implement these requirements. Additionally, we are proposing that facilities will need to report the unplanned openings (including the date, time, duration, and any corrective actions taken) in the semiannual compliance report.

In addition to the proposed work practices, we are also proposing an operational limit of five unplanned openings per year per furnace for existing sources, which is an estimate of the MACT floor level of performance for existing sources. For new sources, we are proposing an operational limit of zero unplanned openings per year because the best performing single source in our database reported zero unplanned openings for the most recent typical year.

We estimate that the costs for the entire industry for these proposed standards would be $1,470,000 and annualized costs would be $239,800, for the eight facilities to comply with these work practice requirements, and that these requirements will result in about 0.5 tpy emissions reductions.

We propose that the limit of 5 unplanned openings per year per furnace and the work practice standards described above are a reasonable

[4] For more information regarding the general use of the UPL and why it is appropriate for calculating MACT floors, see *Use of Upper Prediction Limit for Calculating MACT Floors* (UPL Memo), which is available in the docket for this action.

estimation of the MACT floor level of performance (*i.e.,* represent a reasonable estimate of the average performance of the best performing five sources). Furthermore, we did not identify any cost-effective and appropriate BTF options. Nevertheless, we solicit comments regarding: (1) Whether EPA should change or remove any of the specific work practices described above, and, if so, an explanation including any related analysis to support as to why or why not; (2) whether there are cost-effective BTF options; (3) whether EPA should consider a different number of unplanned openings per year (*e.g.,* 3, 6, or 10 unplanned openings per year, or a different value), and if so, why; (4) whether the limit should be an enforceable compliance limit or an action level that triggers the need to do root cause analyses and take corrective action; and (5) are there furnace design differences that affect operations related to unplanned openings. Furthermore, we solicit comments on the cost estimates for all aspects of these proposed requirements, including costs for the recordkeeping and reporting requirements, and we solicit data and suggestions regarding any other aspect of these proposed requirements that we should consider as we develop the final rule, including any additional data regarding how many unplanned openings have occurred per year (*e.g.,* for the past five years) for the various blast furnaces in the source category.

Further information and analyses (regarding the proposed MACT standard, BTF options and other relevant topics) are available in the document titled *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF* which is available in the docket

2. BF Planned Bleeder Valve Openings

Bleeder valves are opened periodically to allow repair or other maintenance. The furnace is turned down to low idle before valves are opened, which results in lower emissions than during unplanned openings. It is our understanding that planned openings happen up to 2 times per week for repairs or for maintenance for a total average of approximately 15 hours per week per furnace. We estimate that source category emissions resulting from these planned openings are about 1.6 tpy of HAP metals.

We received opacity data from six of the eight operating facilities for planned openings. We reviewed the maximum 6-minute opacity readings for all six facilities. Based on the 2022 data, the two best-performing facilities had maximum 6-minute opacity readings of 0 percent and 6.25 percent, respectively. The average opacity readings at these two facilities are 0 percent and 3.39 percent respectively. The average of the maximum 6-minute opacity values for the best performing five facilities is 7.75 percent (rounded to 8 percent). In calculating the opacity limit, we did not apply the standard UPL approach (described in section III.B of this preamble) because that method has not been used in the past when calculating opacity limits. More information and explanation regarding opacity, especially in the context of EPA emissions standards, is provided in section II.A.2 of this preamble. More information regarding the UFIP sources and the development of proposed standards for UFIP sources are provided in the document titled *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is in the docket for this proposed rule.

We estimate that the ''MACT floor'' is the average of the maximum 6-minute opacity levels, which is 8 percent. We also evaluated a limit of 5 percent opacity as a potential BTF option for existing sources. We also determined based on evaluation of available information that emissions can be minimized from bleeder valve planned openings cost effectively by implementing various actions before the valves are opened such as: (1) Tapping as much liquid (iron and slag) out of the furnace as possible; (2) removing fuel and/or stopping fuel injection into the furnace; and (3) lowering bottom pressure.

Based on our evaluation of available information, pursuant to CAA section 112(d)(2) and (3) for existing sources we are proposing a MACT Floor limit of 8 percent opacity for any 6-minute averaging period for the BF planned bleeder valve openings. For new sources, we are proposing an opacity of 0 percent because based on the available data, the best performing single source had opacity of 0 percent during the planned opening. We are not proposing the BTF option of 5 percent opacity for existing sources because we assume 5 percent opacity may not be feasible for some sources on a consistent basis. We are not proposing any work practices under CAA section 112(h) for the BF planned bleeder valve openings. Facilities will have the flexibility to choose an appropriate approach to meet the opacity limit. We estimate that this proposed standard will result in about 0.41 tpy reduction in HAP metal emissions. The estimated cost is $54,600/yr for the entire category and $6,800/yr per facility. The estimated cost effectiveness is $134,000 per ton of HAP metals.

We solicit comments and additional information regarding these proposed requirements, including: (1) Comments regarding the proposed opacity limits, including the level of the opacity limits and averaging time; (2) whether the EPA should apply the UPL approach (or other statistical approach) to derive the opacity limits for UFIP sources and if so an explanation of the suggested application of the UPL or other statistical approach to derive opacity limits; (3) whether the EPA should promulgate work practices instead of the opacity limits and a description of those work practices; and (4) whether the EPA should promulgate work practices and the opacity limits.

3. BF and BOPF Slag Processing, Handling, and Storage

Slag (liquid waste on the surface of molten iron or steel) is skimmed and transported out of buildings in troughs (or ''runners'') or by using pots to large pits where it cools. Emissions occur during four activities: (1) dumping of hot slag in pits; (2) storing slag in open pits; (3) removing slag from pits with loaders, and; (4) handling (*e.g.,* movement into and out of trucks and slag piles), storage, and processing. Operators can spray water on the slag or use fogging systems, which create and direct fog (tiny water droplets or ice crystals suspended in the air) into the slag area to weigh down and minimize PM (or dust) emissions during dumping, loading, and digging operations. We estimate that about 30 tpy of HAP metals are emitted from slag processing, handling, and storage for the source category.

We received opacity data from seven of the eight operating facilities. We reviewed the maximum 6-minute opacity readings for all seven facilities. The average of the maximum 6-minute opacity values for the best performing five facilities is 9 percent. Based on the 2022 data, the two best-performing facilities in our dataset had maximum opacity readings of 2.5 percent and 5 percent, respectively. The average opacity readings at these two facilities are 0.2 percent and 1.2 percent, respectively. We did not apply the standard UPL approach for the same reasons discussed above. Nevertheless, this average of maximum opacity values suggests that the ''MACT floor'' is approximately 9 percent. We also evaluated a limit of 5 percent opacity as

a potential BTF option. We also determined based on evaluation of available information that emissions can be minimized from slag pits cost effectively with the application of water spray or fogging. Also, other work practices such as installing wind screens, dust suppression misters, a high moisture content of the slag during handling, storage, and processing and using material handling practices can help minimize emissions. Therefore, based on our analyses, pursuant to CAA section 112(d)(2) and (3), for existing sources we are proposing a BTF opacity limit of 5 percent (based on 6-minute averages) for visible emissions from slag pits, and during slag handling, storage, and processing. This will result in an estimated 7.4 tpy reduction in HAP metal emissions. The estimated cost is $308,000 per year for the entire category and $38,500 per year per facility. The estimated cost effectiveness is $41,900 per ton of HAP metals. Regarding new sources, we are proposing an opacity limit of 2.5 percent (based on 6-minute averages) for visible emissions from slag pits, and during slag handling, storage, and processing.

However, regarding the proposed limit for existing sources, we are soliciting comments as to the feasibility of the 5 percent BTF opacity limit for other facilities in the source category, and also soliciting comments as to whether the EPA should set the opacity limit at the MACT floor level (*i.e.,* 9 percent opacity based on 6-minute averages), or possibly at a lower, more stringent value, instead of the 5 percent BTF opacity limit, and if so why, or why not. We also solicit comments and data regarding the proposed opacity limit for new sources.

4. BF Bell Leaks

Large and small bells are part of a lock system above the BF that is used to charge raw materials into the BF without gases escaping. The bells have metal seals that wear down over time from mechanical use and movement of bells (they open to charge, then close when charge is done, frequently, which results in frequent contact between the metal parts, which leads to wear and tear overtime). Overtime, the seals wear down or are damaged, which eventually results in gases being emitted to the atmosphere. Therefore, the bells need to be repaired or replaced periodically to prevent emissions. We estimate that about 76 tpy of HAP metals are emitted from Bell Leaks for the source category.

Based on our evaluation, pursuant to CAA section 112(d)(2) and (3), we are proposing 10 percent opacity as an action level for large bell leaks (not a MACT emissions limit), as described below. We are also proposing that the BF top will need to be observed monthly for visible emissions (VE) with EPA Method 22, 40 CFR part 60, appendix A–7, which determines the presence or absence of a visible plume, to identify leaks, and if VE are detected out of the interbell relief valve (indicating leaks from the large bell), we are proposing that the facility would then need to perform EPA Method 9, 40 CFR part 60, appendix A–4, tests which determines the opacity (*i.e.,* degree to which a plume obscures the background), monthly and if opacity is greater than 10 percent (based on a 3-minute average), the large bell seals will need to be repaired or replaced within 4 months. For the small bell, we are proposing that facilities will need to replace or repair seals prior to a metal throughput limit, specified by the facility, that has been proven and documented to produce no opacity from the small bells. This will result in an estimated 31 tpy reduction in HAP metal emissions. The estimated cost is $935,000 per year for the entire category and $120,000 per facility. The estimated cost effectiveness is $30,000 per ton of HAP metals. There could potentially be some additional incremental costs due to this proposed requirement due to the possible need to repair or replace the seals more frequently than facilities currently do the repairs or replacement to account for additional capital costs and loss of production due to more frequent furnace shutdowns to do such repairs or replacement, however, we have insufficient information to estimate these possible additional incremental costs at this time.

We are soliciting comments regarding these proposed requirements, including whether the opacity action level should be set at a higher or lower percent value and, if so, for what averaging period. We also solicit comments regarding all other aspects of these proposed requirements including the 4-month time period (to repair or replace seals) described above, and the estimated costs (including costs due to loss production, if any) and emissions reductions associated with these proposed requirements.

5. Beaching of Iron From BFs

When the BOPF is stopped suddenly and cannot accept iron, then hot iron from the BF is dumped onto the ground and fumes are emitted. We estimate that less than 1 tpy of HAP metals are emitted from beaching for the source category.

Available data and responses to the 2022 CAA section 114 request indicate that one facility does not have beaching and another facility had not done any beaching for 3 years (2019, 2020, or 2021). Of the remaining six operating facilities, four facilities have full or partial enclosures or use CO_2 to suppress fumes, and all six facilities minimize the height, slope, and speed of beaching. Therefore, we conclude these actions approximately represent the MACT floor level of performance. Furthermore, we did not identify any more stringent cost-effective BTF options. For these reasons, pursuant to CAA section 112(d)(2) and (3) and CAA section 112(h), we are proposing a MACT standard that would require facilities to: (1) Have full or partial enclosures for the beaching process or use CO_2 to suppress fumes; and (2) minimize the height, slope, and speed of beaching. We expect this will result in a small amount of unquantified emission reductions since baseline emissions are already low (less than 1 tpy of HAP) and because most facilities are already following some or all of these work practices. The estimated cost is $55,000 per year for the entire category and an average annual cost of $6,800 per facility. More information regarding the proposed standards, and the BTF options considered, for unregulated UFIP sources is available in the following document: *Unmeasurable Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action.

We solicit comments and additional information regarding all aspects of these proposed beaching requirements.

B. Reconsideration of BF Casthouse and BOPF Shop Standards for Currently Regulated Fugitive Sources Under CAA 112(d)(6) Technology Review for Both New and Existing Sources

1. How did we develop the proposed revised CAA section 112(d)(6) technology review standards for BOPF shop fugitive emissions?

The BOPF shop fugitive emissions occur from hot metal and scrap charging, tapping steel, hot metal transfer, and metallurgical processes. Hoods collect some fugitives and route them to controls. Uncaptured fugitives exhaust through roof vents, doors, or other openings such as removed or damaged sections of the enclosure or building that were not part of the original design. We estimate the current total emissions from BOPF shops in the source category are about 123 tpy of HAP metals (such as manganese, arsenic, chromium and lead). The

current NESHAP has a 20 percent opacity limit for the BOPF shop.

When EPA was developing the 2020 RTR, EPA had very limited data regarding the opacity levels being achieved by facilities at that time and limited data regarding the types of work practices being applied by facilities. The EPA explained in the 2019 proposed rule (84 FR 42704, August 16, 2023), and again in the 2020 final rule (85 FR 42074, July 13, 2020) that EPA did not propose any of these work practices primarily because there were significant uncertainties in the technical assessment of UFIP emissions that included estimates of the baseline UFIP emissions, the estimated HAP reductions that would be achieved by the work practices, and the costs of the work practices. In addition, EPA also stated that there were uncertainties in the effect the work practices would have on facility operations, economics, and safety.

Based on our review and analyses of the CAA section 114 information request responses we received in 2022 and 2023, and further review of the data and analyses the EPA assembled to support the 2020 RTR, we now conclude that a standard comprising a 5 percent opacity limit with several specific work practices is feasible and cost effective. For example, based on the data we received, the maximum 3-minute opacity readings for the BOPF shops at four facilities are less than 5 percent. Furthermore, the use of work practices (described below) by the best performing facilities in the industry leads us to conclude that these work practices are feasible, and accordingly, we are proposing a 5 percent opacity limit (based on 3-minute average) and work practices.

Specifically, we are proposing that facilities will need to do the following: (1) Keep all openings, except roof monitors (vents) and other openings that are part of the designed ventilation of the facility, closed during tapping and material transfer events (the only openings that would be allowed during these events are the roof vents and other openings or vents that are part of the designed ventilation of the facility) to allow for more representative opacity observations from a single opening; (2) have operators conduct regular inspections of BOPF shop structure for unintended openings and leaks; (3) optimize positioning of hot metal ladles with respect to hood face and furnace mouth; (4) monitor opacity twice per month from all openings, or from the one opening known to have the highest opacity, for a full steel cycle, which must include a tapping event; and (5) develop and operate according to an Operating Plan to minimize fugitives and detect openings and leaks. We are proposing that the BOPF Shop Operating Plan shall include:

- An explanation regarding how the facility will address and implement the four specific work practices listed above;
- A maximum hot iron pour/charge rate (pounds/second) for the first 20 seconds of hot metal charge (*i.e.,* the process of adding hot iron from the BF into the basic oxygen process furnace);
- A description of operational conditions of the furnace and secondary emission capture system that must be met prior to hot metal charge, including:
- A minimum flowrate of the secondary emission capture system during hot metal charge;
- A minimum number of times, but at least once, the furnace should be rocked between scrap charge and hot metal charge;
- A maximum furnace tilt angle during hot metal charging: and;
- An outline of procedures to attempt to reduce slopping.

We estimate the costs to implement these WPs will be about $500,000 per year for the source category ($60,000 per facility), and the WPs will achieve about 25 tpy reduction in HAP metal emissions, with cost effectiveness of $19,600 per ton HAP metals.

We solicit comments and additional information regarding these proposed requirements, including: (1) Comments regarding the specific work practices and opacity limit, including the level of the opacity limit, averaging time and frequency of the Method 9 opacity tests to demonstrate compliance; (2) whether the EPA should only promulgate the opacity limit and not include specific work practices; (3) whether the EPA should only include the work practices and not the opacity limit; (4) whether EPA should remove or change any of the specific work practices described above, and if so, an explanation with supporting analysis as to what changes should be made and why. We also are soliciting comments on whether EPA should provide an alternative limit to the 5 percent opacity limit for a small period of time during each cycle, or for a certain time period (*e.g.,* once per month or once per 3-month period), similar to the alternative standard that is in the current subpart FFFFF NESHAP for new top blown BOPF shops, which says that new top blown BOPF shops must not exceed an opacity of ''10 percent, except that one 3-minute period greater than 10 percent but less than 20 percent may occur once per steel production.'' (See 40 CFR part 63, subpart FFFFF), or whether EPA should make the standard, or standards, also dependent on a percentage of operating time.

2. How did we develop the revised CAA section 112(d)(6) technology standards for BF casthouse fugitive emissions?

Fugitive emissions from the BF leave the casthouse through roof vents, doors left open, and other openings. We estimate the current total emissions from BF casthouses in the source category are about 46 tpy of HAP metals (such as manganese, arsenic, chromium and lead). The current NESHAP includes 20 percent opacity limits for the casthouse. Based on review of the CAA section 114 information request responses, we determined that a 5 percent opacity limit is feasible and cost effective. For example, based on recent 2022 data, two facilities (Braddock and Gary) are already below 5 percent opacity (*e.g.,* maximum 6-minute opacity readings of 3.54 and 4.17 percent, respectively). Furthermore, based on thirteen Method 9 tests (each about 2 to 3.5 hours long) in 2018 to 2021 for casthouse fugitives at the Indiana Harbor facility (which are available in the docket for this action), the maximum 6-minute opacity from all of those tests was less than 2 percent opacity. Therefore, we have data indicating that at least three facilities' BFs are already below 5 percent and therefore can meet the proposed 5 percent opacity limit (based on 6-minute averages) with no new control costs, and we expect the other 5 facilities can achieve 5 percent or lower opacity with cost-effective improvements in their operations (as described in the technical memorandum cited below). Therefore, we are proposing a 5 percent opacity limit (based on 6-minute averages) as an update to the CAA section 112(d)(6) technology review and proposing that facilities will need to measure opacity during the tapping operations (at least 2 times per month). We are not proposing specific work practices for the BF casthouse, except that we are proposing that the facilities will need to keep all openings, except roof monitors, closed during tapping and material transfer events (the only openings that would be allowed during these events are those that were present in the original design of the shop). We estimate the costs to achieve and maintain the 5 percent opacity, conduct and record the opacity readings, and ensure the openings (described above) are closed will be approximately $740,000 per year for the source category ($93,000 per facility). We estimate that these actions would

achieve roughly 14.4 tpy reduction in emissions of HAP metals, with a cost-effectiveness of about $51,400 per ton HAP metals. Additional information regarding the emissions estimates and the cost calculations for BOPF shop and casthouse is available in the following documents: *Unmeasured Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action.

EPA solicits comments regarding any suggested modifications to the BF casthouse proposed standards, with thorough explanations to support any suggestions with regard to opacity limits and/or work practices (and suggested regulatory text) including those described in an email from Paul Balserak of the AISI and in an attachment to that email titled: *II&S DRAFT PROPOSED RULE UFIP LANGUAGE, February 22, 2023,* which are available in the docket for this action. However, we received this information too late for us to be able to review and analyze for this proposal. We solicit comments on the information that industry representatives provided including whether EPA should adopt some or all of these suggestions for the final rule, and a thorough explanation including supporting analysis as to why, or why not. We also solicit comments regarding whether EPA should provide an alternative to the 5 percent opacity limit for the BF casthouse, such as the potential alternative described above for top blown BOPF shops opacity, or some other type of alternative, and if so, an explanation of that possible alternative and why, or whether EPA should make the standard, or standards, also dependent on a percentage of operating time.

A summary of estimated annual costs, HAP metal emission reductions, and cost-effectiveness for the proposed standards of each UFIP source are summarized in Table 3.

TABLE 3—ESTIMATED ANNUAL COSTS, HAP METAL EMISSION REDUCTIONS, AND COST-EFFECTIVENESS FOR PROPOSED UFIP STANDARDS

Source	Annualized costs		HAP metal reduction (tpy)	Cost-effectiveness ($/ton HAP removed)
	Total for industry	Average per facility		
BF Unplanned Openings	$239,800	$30,000	0.5	$478,800
BF Planned Openings	54,600	6,800	0.41	134,000
Slag Handling & Storage	308,000	38,500	7.4	41,900
BF Bell Leaks	935,000	120,000	31	30,000
BF Iron Beaching	55,000	6,800	0.0035	15,800,000
BOPF Shop Fugitives	500,000	60,000	25	19,600
BF Casthouse Fugitives	740,000	93,000	14.4	51,400
Total for the 7 UFIP sources	2,828,200	353,500	79	35,924

C. Results of Fenceline Monitoring Data Analyses

In the 2020 RTR, we identified arsenic and chromium as the HAP metals driving the highest risk. Lead also had relatively high emissions estimates in the RTR proposal and is a criteria air pollutant with the potential to cause significant adverse health effects. Therefore, with our 2022 CAA section 114 information requests, we directed certain facilities to monitor these three HAP metals along their fencelines using the sampling method described in 40 CFR part 50, Appendix B. We requested fenceline data (*i.e.,* measured concentrations of the pollutant in the air at, or near, the fenceline in units of micrograms per cubic meter of air (μg/m^3)) for arsenic, chromium, and lead from four facilities at a minimum of four sampling locations per facility (or a total of 16 monitoring sites for the category) using Method 40 CFR part 50, appendix B. Each sampling period lasted 24 hours with five-day intervals in between each sampling period for a total of 6 months (*i.e.,* facilities conducted air sampling for 24 hours every sixth day for a six-month period at each site). These results were averaged at all sampling locations and periods for each facility, resulting in a six-month average concentration for each metal at each of the 16 fenceline locations.

1. Lead and Arsenic Results

For lead, the highest measured 6-month average fenceline concentration (from the 2022–2023 CAA section 114 request sampling) is 3 times greater than the highest modeled concentration for the example facility (US Steel Gary) evaluated in the 2019 RTR proposed rule (84 FR 42704, August 16, 2019) and the 2020 RTR final rule (85 FR 42074, July 13, 2020).

We compared the average 6-month fenceline measurements at each of the 16 monitoring locations to the Pb National Ambient Air Quality Standard (NAAQS), which is 0.15 μg/m^3 (based on a three-month rolling average). For all locations at all facilities, the averages were well below the NAAQS level, with the highest average only 20 percent of the NAAQS, indicating that lead concentrations are below levels of concern at the fenceline for this source category.

For arsenic, the average concentrations measured at the fencelines of the four facilities ranged from 0.001 to 0.015 ug/m^3. Compared to the 2019–2020 modeled results, the highest measured fenceline concentration for arsenic is 6 times higher than the highest modeled concentration at the same example facility.

2. Chromium/Chromium VI Results

Chromium concentrations measured at the fencelines of the four facilities ranged from 0.001 to 0.175 ug/m^3. Compared to the 2019–2020 modeled results, the highest measured fenceline concentration of Cr is 28 times higher than the highest modeled Cr concentration at the same example facility.

Chromium has the highest potential for adverse health effects when it is in the chromium VI oxidized state (Cr^{6+}), which is toxic and classified as a human carcinogen; therefore, we estimated the percentage of total chromium at the fenceline that is Cr^{6+}. To do so, we used a combination of previous emissions data from the emissions release stacks from the 2020 RTR database and values provided by industry—from ambient monitoring data from a site in Michigan that is approximately 250 meters from the fenceline of an integrated iron and steel facility—to determine a range of

ratios for Cr^{6+} to total Cr. The stack testing data from the EPA's RTR proposed and final rules and the recent submittal from industry regarding the ambient monitoring data are provided in the following documents: *Integrated Iron and Steel Risk and Technology Review: Point Source Data Summary Memorandum* (*IIS_Data_Memo_05–01–19–PROPOSAL–RTI.pdf)* and *DRAFT: Review of Available Hexavalent and Total Chromium Ambient Monitoring Data (2022–12–16 427pm Draft—Review of Hex Chrome to Chrome Ambient Air Data—Copy-c.pdf),* which can be found in the docket.

The stack testing data collected from the 2011 Integrated Iron and Steel Manufacturing Facilities CAA section 114 request to industry provided ratios of 10 percent to 39 percent of total Cr that is Cr^{6+} for secondary and primary BOPF units, respectively. These data are presented in the technical memorandum titled *Integrated Iron and Steel Risk and Technology Review: Point Source Data Summary,* which is available in the docket for the 2020 RTR final rule. Further inspection into the data from this request revealed three issues with the values of Cr^{6+} and total Cr, as follows: (1) Some values of Cr^{6+} were higher than total Cr, which is scientifically impossible; (2) one value of Cr^{6+} was equal to total Cr, which we expect is quite improbable because only one value from one facility of the total 22 values from 11 facilities (provided in the 2020 document cited above) reported equal results for Cr^{6+} and total chromium; and (3) there were a few extremely high and low outliers. The data that fell under each of these three categories were removed, and the ratio of Cr^{6+} to total Cr was recalculated. This resulted in a new estimated range of ratios from 10 percent to 18 percent of the total Cr being in the Cr^{6+} form for secondary and primary BOPF units, respectively.

In addition, industry provided feedback on the original ratio range of 10 percent to 39 percent Cr^{6+} with data supporting a much lower ratio, around 1 percent. They provided ratios from ambient air data collected from 2007–2012 at an EPA air toxics monitor approximately 250 meters from the Dearborn, MI Integrated Iron and Steel facility as well as ratios from a Detroit Air Toxics Initiative (DATI) study in 2001 and 2006. The DATI study found ratios from 0.98 percent to 1.18 percent Cr^{6+}, while the Dearborn air monitoring analysis found ratios from 0.68 percent to 0.97 percent Cr^{6+}. The DATI study and other Michigan data mentioned above are available in the following document: *2022–12–16 427pm Draft—Review of Hex Chrome to Chrome Ambient Air Data—Copy-c.pdf,* which is in the docket for this action.

After considering all analysis, we concluded that an estimated range for the ratio of Cr^{6+} to total Cr at the fenceline is 1 percent to 18 percent and applied this range to the average total chromium fenceline measurements to calculate lower- and upper-bound Cr^{6+} fenceline concentrations. The range of Cr^{6+} concentrations at the fenceline across all four facilities using these ratios is 0.0001 to 0.0315 ug/m^3. When compared to the 2020 modeled results, the highest measured concentration of Cr^{6+} at the fenceline was anywhere from 2 to 32 times higher than the highest concentration modeled. This indicates Cr and Cr^{6+} (using a ratio of 1 percent to 18 percent to estimate measurements at the fenceline) emissions were underestimated in the 2020 RTR risk modeling assessment. We expect this difference between modeled and monitored levels is mainly due to an underestimation of fugitive Cr emissions in the RTR.

D. What are the proposed decisions based on our fenceline monitoring data analysis, and what is the rationale for those decisions?

Based on our analysis of the available data and reductions we expect would be achieved by the proposed work practices and opacity limits described above in sections IV.A and B, we are proposing a fenceline monitoring requirement in the NESHAP pursuant to CAA section 112(d)(6). Fenceline monitoring refers to the placement of monitors along the perimeter of a facility to measure pollutant concentrations. Coupled with requirements for root cause analysis and corrective action upon triggering an actionable level, this work practice standard is a development in practices considered under CAA section 112(d)(6) for the purposes of managing fugitive emissions. The measurement of these pollutant concentrations and comparison to concentrations estimated from mass emissions via dispersion modeling can be used to ground-truth emission estimates from a facility's emissions inventory. If concentrations at the fenceline are greater than expected, the likely cause is that there are underreported or unknown emission sources affecting the monitors. In addition to the direct indication that emissions may be higher than inventories would suggest, fenceline monitoring provides information on the location of potential emissions sources. Further, when used with a mitigation strategy, such as root cause analysis and corrective action upon exceedance of an action level, fenceline monitoring can be effective in reducing emissions and reducing the uncertainty associated with emissions estimation and characterization. Finally, public reporting of fenceline monitoring data provides public transparency and greater visibility, leading to more focus and effort in reducing emissions.

Specifically, for the Integrated Iron and Steel Manufacturing NESHAP, we are proposing that facilities must install four ambient air monitors at or near the fenceline at appropriate locations around the perimeter of the facility, regardless of facility size, based on a site specific plan approved by the EPA and collect and analyze samples for total chromium every sixth day, as well as implement the following work practice requirement: if an installed fenceline monitor has a 12-month rolling average delta c concentration, calculated as the annual average of the highest sample value for a given sample period minus the lowest sample value measured during that sample, that is above the proposed action level of 0.1 μg/m^3 for total chromium, the facility must conduct a root cause analysis and take corrective action to prevent additional exceedances. Data will be reported electronically to the EPA's Compliance and Emissions Data Reporting Interface (CEDRI) on a quarterly basis and subsequently available to the public via the Web Factor Information Retrieval system (WebFIRE) website. We solicit comments regarding this proposed electronic reporting, specifically whether when, when required, a corrective action plan should be submitted via CEDRI and subsequently available through WebFIRE, subject to CBI limitations.

We chose to only propose fenceline measurements for chromium because it is found to be a good surrogate for other HAP metals, especially arsenic, which was the other risk driving HAP metal in the 2020 RTR risk analyses (as described in section IV.C of this preamble). Arsenic values at the fenceline are found to correlate approximately 90% with chromium values at the fenceline according to linear regression. Thus, the fenceline requirement for chromium will allow for the effective management of fugitive emissions of other HAP metals.

We derived the proposed action level of 0.1 μg/m^3 by first evaluating all the fenceline Cr results to determine the highest measured 6-month delta c average level across all facilities (which was determined to be 0.154 μg/m^3 at the US Steel Gary facility). The 2nd highest 6-month average monitoring delta c

result across all facilities was 0.115 μg/m³ at the Granite City facility. Both other facilities (Cleveland Works and Burns Harbor) have delta c 6-month averages below 0.08 μg/m³. To establish the proposed action level, we evaluated the estimated reductions of HAP metals that we expect will be achieved at Gary through the proposed work practices and opacity limits. We estimate that the Gary facility will achieve at least a 20 percent reduction in HAP metals by complying with the proposed opacity limits and work practices. A 20 percent reduction would result in an estimated highest 6-month delta c concentration of about 0.123 μg/m³. Because of the variability and limitations in the data, to establish the proposed action level we rounded off this highest 6-month value (*i.e.,* 0.122) to one significant figure (*i.e.,* 0.1 μg/m³). We determined that more significant figures would not be appropriate based on such a data set. Therefore, we are proposing 0.1 μg/m³ as the action level for the fenceline monitoring requirement. Given that: (1) Two of the four facilities are already below 0.08 μg/m³; (2) we project that another facility (Granite City) will be below 0.1 after implementation of the work practices and opacity limits; and (3) since the fourth facility (Gary) is expected to have post control levels that are very close to 0.1 μg/m³ (and round-off to 0.1 μg/m³) we propose that an action level of 0.1 μg/m³ is appropriate and will ensure the effective management of fugitive emissions of other HAP metals.

We also considered a potential action level of 0.08 μg/m³ or 0.09 μg/m³ based in part on the following information. As mentioned above, two of the four facilities already have 6-month delta c averages below 0.08 μg/m³ and one facility (Granite City) is expected to be at 0.09 μg/m³ after implementation of the work practices and opacity limits. Furthermore, the fourth facility would only need to achieve about a 42% reduction of UFIP emissions, therefore we think an action level of 0.09 μg/m³ (or some other level such as 0.08 μg/m3) might be appropriate and cost effective. Therefore, we solicit comments and information as to whether an action level of 0.09 μg/m³ (or some other level such as 0.08 μg/m³) would be more appropriate than the proposed 0.1 μg/m³ action level, and if so, why.

Furthermore, we are proposing to also include a sunset provision whereby if the 12-month average values remain 50 percent below (or lower) than the action level (*i.e.,* below 0.05 μg/m³) for a 24-month period, then that facility would not need to continue with fenceline monitoring as long as they continue to comply with all other proposed requirements described in this proposed rule along with all other requirements already established in the current NESHAP. We solicit comments regarding this proposed sunset provision, including whether a reduced frequency of monitoring would be more appropriate than a complete termination of such monitoring, and if so, what frequency would be appropriate, or whether a reduced number of monitors would be more appropriate (*e.g.,* allow removal of each monitor that remains below the 0.05 μg/m³ for a period of time).

More information regarding the estimated reductions of fugitive emissions are provided in the document titled *Unmeasurable Fugitive and Intermittent Particulate Emissions and Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action.

We expect that the proposed combination of work practices and opacity limits described above in sections IV.A and B will likely ensure fenceline concentrations remain below this action level most, if not all, of the time, so we expect the only costs for this requirement will be the costs for developing the plans, setting up monitoring equipment, collecting and analyzing the samples, and reporting the results. The estimated cost for this requirement is $25,000 capital cost and $41,000/yr in annual costs per monitor, $100,000 capital costs and $164,000/yr in annual costs per facility, and $800,000 capital costs and $1.3M/yr in annual costs for the entire source category. This includes equipment, installation, lab costs, and maintenance and labor.

E. Proposed Standards To Address Unregulated Point Sources for Both New and Existing Sources

In addition to the unregulated UFIP sources, we identified five unregulated HAP from sinter plant point sources (CS_2, COS, HCl, HF, and Hg), three unregulated HAP (D/F, HCl and THC [as a surrogate for organic HAP other than D/F]) from BF stove and BOPF point sources, and two unregulated HAP (HCl and THC) from BF point sources.

The proposed MACT limits for HCl and THC from BF stove point sources were calculated based on data from nine runs each at two different facilities. Six of these runs had no production data or lb/ton emissions data in the test report. The lb/ton emissions values for these six runs were calculated using the average of the BF stove production values in the three test runs from the facility's 2012 HAP metal emissions test report.

The proposed MACT limit for THC from BOPF point sources were calculated based on data from six runs at two different facilities. Three of these runs had no production data or lb/ton emissions data in the test report. The lb/ton emissions values for these three runs were calculated using the average of the BOPF production values in the three test runs from the facility's 2012 HAP metal emissions test report.

We did not identify any cost-effective BTF options for these 13 unregulated HAP. The BTF options we considered and the estimated costs and reductions that the BTF options would achieve are described in the *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action. Therefore, we are proposing MACT floor limits for the five unregulated HAP from sinter plant point sources, the three unregulated HAP from BF stove and BOPF point sources, and the two unregulated HAP from BF casthouse control devices, as shown in Table 4. We expect no control costs or emissions reductions as a result of these emissions limits, except there will be some costs for compliance testing, recordkeeping, and reporting which are described in sections V.C and VIII.B of this preamble.

As explained above, we are proposing MACT floor limits (not BTF limits), so we think all facilities should be able to comply with these MACT floor limits with their current controls (*i.e.,* we expect there will be no new control costs for the new MACT floor limits). Nevertheless, EPA solicits comment regarding this conclusion.

TABLE 4—ESTIMATED HAP EMISSIONS AND PROPOSED MACT LIMITS FOR POINT SOURCES

Process	HAP	Estimated source category emissions	Proposed MACT limit
Sinter Plants	CS_2	23 tpy	Existing and new sources: 0.028 lb/ton sinter.
Sinter Plants	COS	72 tpy	Existing sources: 0.064 lb/ton sinter. New sources: 0.030 lb/ton sinter.
Sinter Plants	HCl	12 tpy	Existing sources: 0.025 lb/ton sinter. New sources: 0.0012 lb/ton sinter.
Sinter Plants	HF	1.3 tpy	Existing and new sources: 0.0011 lb/ton sinter.
Sinter Plants	Hg	55 pounds/yr	Existing sources: 3.5e–5 lb/ton sinter. New sources: 1.2e–5 lb/ton sinter.
BF casthouse control devices	HCl	1.4 tpy	Existing sources: 0.0013 lb/ton iron. New sources: 5.9e–4 lb/ton iron.
BF casthouse control devices	THC	270 tpy	Existing sources: 0.092 lb/ton iron. New sources: 0.035 lb/ton iron.
BOPF	D/F (TEQ[1])	3.6 grams/yr	Existing and new sources: 4.7e–8 lb/ton steel.
BOPF	HCl	200 tpy	Existing sources: 0.078 lb/ton steel. New sources: 1.9e–4 lb/ton steel.
BOPF	THC	13 tpy	Existing sources: 0.04 lb/ton steel. New sources: 0.0017 lb/ton steel.
BF Stove	D/F (TEQ)	0.076 grams/year	Existing and new sources: 3.8e–10 lb/ton iron.
BF Stove	HCl	4.5 tpy	Existing sources: 5.2e–4 lb/ton iron. New sources: 1.4e–4 lb/ton iron.
BF Stove	THC	200 tpy	Existing sources: 0.1 lb/ton iron. New sources: 0.0011 lb/ton iron.

[1] Toxic equivalents.

The EPA solicits comment on the data used to calculate the MACT floor limits (shown in Table 4). EPA also welcomes the submittal of more test data from stakeholders, as soon as possible, to further inform the development of appropriate MACT limits for the final rule. We are also soliciting comments on whether the format of the limits (lbs/ton) for BF Stoves is most appropriate or whether a different format would be more appropriate for the BF Stoves such as lbs of HAP per cubic foot of gas or lbs of HAP per British thermal unit (BTU). EPA also solicits comment on whether an averaging compliance alternative should be considered for the NESHAP to demonstrate compliance with the limits and if so what types of alternatives should be considered. We also solicit comment on whether there are surrogates that are representative of any of the new HAP limits that EPA should consider and, if so, why, including an explanation as to how that surrogate might be appropriate for any of these HAP.

F. Reconsideration of Standards for D/F and PAH for Sinter Plants Under CAA Section 112(d)(6) Technology Review for Both New and Existing Sources

As part of our updates to the CAA section 112(d)(6) review, we analyzed available test data for D/F and PAH from sinter plants. We also evaluated potential emissions limits for D/F and PAHs. First, we developed a regulatory option that reflects the current control technologies and practices (current performance) at the existing sinter plants at the three source category facilities that have sinter plants. The sinter plants are currently controlled with baghouses or wet scrubbers. To derive an emissions limit that reflects current controls, we used the UPL approach we typically use for calculation of MACT floor limits (described above in section III.B). Using the UPL method, we calculated an emissions limit of 3.5E–08 lbs/ton of sinter for D/F (TEQ) and an emissions limit of 5.9E–03 lbs/ton for PAHs for existing sinter plant windboxes and limits of 3.1E–09 lbs/ton of sinter for D/F (TEQ) and 1.5E–03 lbs/ton of sinter for PAHs for new sinter plant windboxes.

Second, as part of the technology review, we analyzed and evaluated an option based on the addition of new controls (*i.e.,* activated carbon injection or ACI) to reduce emissions of D/F and PAHs. We estimate the total capital costs of these controls would be $950,000, the annual costs would be $2.3 million, and the controls would achieve 8 grams per year reduction of D/F TEQ and 5.4 tpy reduction of PAHs, with cost effectiveness of $287,000 per gram and $340,000 per ton, respectively.

Based on that analysis and evaluation of regulatory options, we conclude that the second option (*i.e.,* addition of ACI) is not cost effective. This conclusion is consistent with the EPA's decisions made in the 2020 RTR final rule as part of our ample margin of safety analysis for D/F in 2020. Therefore, we are proposing the emissions limits of 3.5E–08 lbs/ton of sinter for D/F (TEQ) and 5.9E–03 lbs/ton of sinter for PAHs for existing sinter plant windboxes, and limits of 3.1E–09 lbs/ton of sinter for D/F (TEQ) and 1.5E–03 lbs/ton of sinter for PAHs for new sinter plant windboxes that reflect current performance. We estimate all three facilities with sinter plants would be able to meet these limits with no additional controls so there will be no emissions reductions with these new existing standards. The estimated costs for compliance tests are $50,000 to $75,000 per facility, once every 5 years. Furthermore, we do not expect any new sinter plants will be constructed in the foreseeable future. Therefore, we expect no impacts due to these new source emissions limits.

Regarding the second option described above (*i.e.,* an emissions limit based on addition of ACI), although we are not proposing this option, we solicit comments regarding this option, including the cost effectiveness determination and whether or not EPA should establish a tighter limit (based on application of ACI) and if so why and analysis to support that conclusion. For more details regarding our data and analyses of options, see the technical memorandum titled: *Maximum Achievable Control Technology Standard Calculations, Cost Impacts, and Beyond-the-Floor Cost Impacts for Integrated Iron and Steel Facilities under 40 CFR part 63, subpart FFFFF,* which is available in the docket for this action.

EPA also solicits comment on whether the proposed new limits for dioxin/furans and PAHs are appropriate

or if EPA should instead maintain the current approach in the NESHAP which is that the sinter plant oil content limit of the feedstock to the sinter plant and/or the VOC emission limit from the windbox exhaust stream are surrogates for the dioxin/furans and PAH emissions for sinter plants.

G. Adding 1-Bromopropane to List of HAP

On January 5, 2022, the EPA published a final rule amending the list of hazardous air pollutants (HAP) under the CAA to add 1-bromopropane (1–BP) in response to public petitions previously granted by the EPA. (87 FR 393). Consequently, as each NESHAP is reviewed, we are evaluating whether the addition of 1–BP to the CAA section 112 HAP list impacts the source category. For the Integrated Iron and Steel Manufacturing Facilities source category, we conclude that the inclusion of 1–BP as a regulated HAP would not impact the representativeness of the MACT standard because, based on available information, we have no evidence that 1–BP is emitted from this source category. As a result, no changes are being proposed to the subpart FFFFF NESHAP based on the January 2022 rule adding 1–BP to the list of HAP. Nevertheless, we are requesting comments regarding the use of 1–BP and any potential emissions of 1–BP from this source category.

H. What compliance dates are we proposing?

Amendments to the Integrated Iron and Steel Manufacturing Facilities NESHAP proposed in this rulemaking for adoption under CAA section 112(d)(2), (3), and (6) and 112(h) are subject to the compliance deadlines outlined in the CAA under section 112(i). For existing sources, CAA section 112(i)(3) provides there shall be compliance ''as expeditiously as practicable, but in no event later than 3 years after the effective date of such standard . . . .'' subject to certain exemptions further detailed in the statute.[5] In determining what compliance period is as ''expeditious as practicable,'' we consider the amount of time needed to plan and construct projects and change operating procedures. As provided in CAA section 112(i), all new affected sources must comply with these provisions by the effective date of the final amendments to the Integrated Iron and Steel Manufacturing Facilities NESHAP or upon startup, whichever is later.

All affected facilities would have to continue to meet the current provisions of 40 CFR part 63, subpart FFFFF until the applicable compliance date of the amended rule. The final action is expected to qualify under the definition in 5 U.S.C. 804(2), so the effective date of the final rule will be 60 days after the promulgation date as specified in the Congressional Review Act. See 5 U.S.C. 801(a)(3)(A).

With regard to the new emissions limits for sinter plant windboxes, since we have test data from all three existing sinter plants except for HF from one facility, and because these facilities already have controls in place to meet the new emissions limits (as described above), we expect facilities will be able to comply with the new emissions limits in a relatively short time period after the final rule is published in the **Federal Register**. However, we expect the sources will need some time (*e.g.,* up to 6 months) to conduct applicability reviews, conduct performance testing, and implement monitoring to comply with the new emissions limits. Therefore, for all affected sinter plant windbox sources that commence construction or reconstruction on or before July 31, 2023, we are proposing that owners or operators must comply with the new emissions limits within 6 months after the promulgation date of the final rule.

With regard to fenceline monitoring requirements, a method for the fenceline measurement of metals has not yet been promulgated. Once the method is promulgated, we expect that sources will need up to 6 months to begin the required monitoring because they first need to develop fenceline monitoring plans, submit those plans to the EPA for review and approval, and then they will require time to set up all the fenceline monitors which will include, in some cases, installing new electric powerlines to support the new monitors. Therefore, for all affected sources that commence construction or reconstruction on or before July 31, 2023, we are proposing that owners or operators must comply with the proposed fenceline monitoring requirements within 1 year of promulgation of the fenceline method for metals or 2 years after the promulgation date of the final rule, whichever is later. This would mean that facilities would need to begin the fenceline monitoring no later than 1 year after the promulgation date of the fenceline method or 2 years after promulgation of the rule. The EPA intends to propose a metals fenceline method sometime in 2024 through a separate action. Subsequently, the proposed action level and requirements for root cause analyses and other actions would apply 12 months later since the action level is based on 12-month rolling average concentrations.

With regard to the proposed opacity limits and work practice standards, although we do not expect the need for any additional add-on controls, we expect facilities need up to 12 months to install and operate various types of equipment, such as devices to continuously measure/monitor material levels in BFs with alarms to inform operators of static conditions which increase likelihood of unplanned bleeder valve openings; instruments on the BF to monitor temperature and pressure; water spray equipment or fogging equipment to minimize emissions from slag; full or partial enclosures or CO_2 gas suppression equipment to minimize emissions during beaching; improved hooding or fans to increase draft velocities to capture more fugitives in BF casthouse or BOPF shop; or improved runner covers in the BF casthouses. Furthermore, facilities may need several months to repair unintended openings in the BF casthouse or BOPF shop that are not part of the original or modified building design. Therefore, for all affected sources that commence construction or reconstruction on or before July 31, 2023, we are proposing that owners or operators must comply with the opacity limits and work practices for the seven UFIP sources described above in sections IV.A and B within 12 months after promulgation.

With regard to the new emissions limits for HCl, THC, and D/F for BFs and BOPFs, as explained above in section IV.E, we expect all facilities will be able to comply with the new emissions limits without the need for additional controls because all BFs and BOPFs are similar and have similar controls. Therefore, for all affected BF and BOPF sources that commence construction or reconstruction on or before July 31, 2023, we are proposing that owners or operators must comply within 6 months after the promulgation date of the final rule.

For all affected sources that commence construction or reconstruction after July 31, 2023, we are proposing that owners or operators must comply with the all the proposed new and revised provisions by the

[5] *Ass'n of Battery Recyclers* v. *EPA,* 716 F.3d 667, 672 (D.C. Cir. 2013) (stating that ''section 112(i)(3)'s 3-year maximum compliance period applies generally to 'any emission standard . . . promulgated under [CAA section 112]''' (quoting 42 U.S.C. 7412(i)(3) (brackets in original)).

effective date of the final rule (or upon startup, whichever is later). All compliance dates for this proposed rule are summarized in Table 5.

TABLE 5—SUMMARY OF COMPLIANCE DATES FOR THE PROPOSED RULE

Source(s)	Rule requirement	Compliance date
All affected sinter plant windbox sources that commence construction or reconstruction on or before July 31, 2023.	Proposed new emissions limits for mercury, HCl, HF, CS_2, COS, D/F, and PAH.	6 months after the promulgation date of the final rule.
All affected sources that commence construction or reconstruction on or before July 31, 2023.	Proposed fenceline monitoring requirements ..	1 year after the promulgation of the fenceline method for metals or 2 years after the promulgation date of the final rule, whichever is later.
	Proposed opacity limits and work practices for the seven UFIP sources.	12 months after the promulgation date of the final rule.
All affected BF and BOPF sources that commence construction or reconstruction on or before July 31, 2023.	Proposed new emissions limits for HCl, THC, and D/F.	6 months after the promulgation date of the final rule.
All affected sources that commence construction or reconstruction after July 31, 2023.	All proposed new and revised provisions	Effective date of the final rule (or upon startup, whichever is later).

We solicit comment on these proposed compliance periods, and we specifically request submission of information from sources in this source category regarding specific actions that would need to be undertaken to comply with the proposed amended provisions and the time needed to make the adjustments for compliance with any of the revised provisions. We also solicit comment on whether and how efforts to meet the proposed compliance periods would impact decarbonization efforts or other efforts to address hazardous air pollutants. We note that information provided could result in changes to the proposed compliance dates, if appropriate.

V. Summary of Cost, Environmental, and Economic Impacts

A. What are the affected sources?

The affected sources are facilities in the Integrated Iron and Steel Manufacturing Facilities source category. This includes any facility engaged in producing steel from iron ore. Integrated iron and steel manufacturing includes the following processes: sinter production, iron production, iron preparation (hot metal desulfurization), and steel production. The iron production process includes the production of iron in BFs by the reduction of iron-bearing materials with a hot gas. The steel production process includes BOPF. Based on the data we have, there are eight operating integrated iron and steel manufacturing facilities subject to this NESHAP, and one idle facility.

B. What are the air quality impacts?

We project emissions reductions of about 79 tpy of HAP metals and about 560 tpy of $PM_{2.5}$ from UFIP sources in the Integrated Iron and Steel Manufacturing Facilities source category due to the new and revised standards for UFIP sources.

C. What are the cost impacts?

The estimated capital costs are $5.4M and annualized costs are $2.8M per year for the source category for the new UFIP control requirements. Also, compliance testing for all the new standards is estimated to cost about $1.7M once every 5 years for the source category (which equates to about an average of roughly $320,000 per year). The estimated cost breakdown for the fenceline monitoring requirement is $25,000 capital cost and $41,100 annual operating costs per monitor, $100,000 capital costs and $164,000 annual operating costs per facility, and $800,000 capital costs and $1.3M annual operating costs for the source category (assumes 8 operating facilities). Additional monitoring, recordkeeping, and reporting requirements associated with the proposed rule are expected to cost $7,500 per facility per year ($60,000 for the source category per year, assuming eight facilities). The total estimated capital costs are $6.2 million and total estimated annualized costs are $4.9 million for all the proposed requirements for the source category. However, annual costs could decrease after facilities complete 2 years of fenceline monitoring because we are proposing a sunset provision whereby if facilities remain below the action level for 2 full years, they can terminate the fenceline monitoring as long as they continue to comply with all other rule requirements. There may be some energy savings from reducing leaks of BF gas from bells, which is one of the work practices described in this preamble, however those potential savings have not been quantified.

D. What are the economic impacts?

The EPA conducted an economic impact analysis for the proposed rule in the Regulatory Impact Analysis (RIA), which is available in the docket for this action. If the compliance costs, which are key inputs to an economic impact analysis, are small relative to the receipts of the affected industries, then the impact analysis may consist of a calculation of annual (or annualized) costs as a percent of sales for affected parent companies. This type of analysis is often applied when a partial equilibrium or more complex economic impact analysis approach is deemed unnecessary given the expected size of the impacts. The annualized cost per sales for a company represents the maximum price increase in the affected product or service needed for the company to completely recover the annualized costs imposed by the regulation. We conducted a cost-to-sales analysis to estimate the economic impacts of this proposal, given that the EAV of the compliance costs over the period 2025–2034 are $4.6 million using a 7 percent or a 3 percent discount rate in 2022 dollars, which is small relative to the revenues of the steel industry.

There are two parent companies directly affected by the proposal: Cleveland-Cliffs, Inc. and U.S. Steel. Each reported greater than $20 billion in revenue in 2021. The EPA estimated the annualized compliance cost each firm is expected to incur and determined the estimated cost-to-sales ratio for each firm is less than 0.02 percent. Therefore, the projected economic impacts of the expected compliance costs of the proposal are likely to be small. The EPA also conducted a small business screening to determine the possible impacts of the proposed rule on small

businesses. Based on the Small Business Administration size standards and Cleveland-Cliffs, Inc. and U.S. Steel employment information, this source category has no small businesses.

E. What are the benefits?

The proposed UFIP emissions work practices to reduce HAP emissions (with concurrent control of $PM_{2.5}$) could improve air quality and the health of persons living in surrounding communities. The proposed opacity limits and UFIP work practices are expected to reduce about 79 tpy of HAP metal emissions, including emissions of manganese, lead, arsenic, and chromium. Due to methodology and data limitations, we did not attempt to monetize the health benefits of reductions in HAP in this analysis. Instead, we are providing a qualitative discussion of the health effects associated with HAP emitted from sources subject to control under the proposed action in section 4.2 of the RIA, available in the docket for this action. The EPA remains committed to improving methods for estimating HAP benefits by continuing to explore additional aspects of HAP-related risk from the integrated iron and steel manufacturing sector, including the distribution of that risk.

The proposed opacity limits and UFIP work practices are also estimated to reduce $PM_{2.5}$ emissions by about 560 tpy for the source category. The EPA estimated monetized benefits related to avoided premature mortality and morbidity associated with reduced exposure to $PM_{2.5}$ for 2025–2034. The present-value (PV) of the short-term benefits for the proposed rule range from $2.3 billion at a 3 percent discount rate to $1.7 billion at a 7 percent discount rate with an equivalent annualized value (EAV) of $260 million and $220 million, respectively. The EAV represents a flow of constant annual values that would yield a sum equivalent to the PV. The PV of the long-term benefits for the proposed rule range from $2.4 billion at a 3 percent discount rate to $1.7 billion at a 7 percent discount rate with an EAV of $280 million and $230 million, respectively. All estimates are reported in 2022 dollars. For the full set of underlying calculations see the *Integrated Iron and Steel Benefits workbook,* available in the docket for this action.

F. What analysis of environmental justice did we conduct?

Executive Order 12898 directs EPA to identify the populations of concern who are most likely to experience unequal burdens from environmental harms, which are specifically minority populations (people of color), low-income populations, and Indigenous peoples (59 FR 7629, February 16, 1994). Additionally, Executive Order 14096 built upon and supplemented that order (88 FR 25251) (Apr. 26, 2023). For this action, pursuant to the Executive Orders, the EPA conducted an assessment of the impacts that would result from the proposed rule amendments, if promulgated, on communities with environmental justice concerns living near Integrated Iron and Steel facilities.

Consistent with the EPA's commitment to integrating environmental justice (EJ) in the Agency's actions, the Agency has carefully considered the impacts of this action on communities with EJ concerns. The EPA defines EJ as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income, with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' [6] The EPA further defines 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.'' In recognizing that communities with EJ concerns often bear an unequal burden of environmental harms and risks, the EPA continues to consider ways of protecting them from adverse public health and environmental effects of air pollution. For purposes of analyzing regulatory impacts, the EPA relies upon its June 2016 *Technical Guidance for Assessing Environmental Justice in Regulatory Analysis,*[7] which provides recommendations that encourage analysts to conduct the highest quality analysis feasible, recognizing that data limitations, time, resource constraints, and analytical challenges will vary by media and circumstance. The Technical Guidance states that a regulatory action may involve potential EJ concerns if it could: (1) Create new disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; (2) exacerbate existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples; or (3) present opportunities to address existing disproportionate impacts on minority populations, low-income populations, and/or Indigenous peoples through this action under development.

To examine the potential for any EJ issues that might be associated with Integrated Iron and Steel Manufacturing Facilities sources, we performed a proximity demographic analysis, which is an assessment of individual demographic groups of the populations living within 5 km and 50 km of the facilities. The EPA then compared the data from this analysis to the national average for each of the demographic groups. This approach is consistent with EPA's longstanding approach for evaluating the potential for impacts on communities with EJ concerns.

The results of the proximity demographic analysis (see Table 6) indicate that, for populations within 5 km of the nine integrated iron and steel facilities, the percent of the population that is African American is more than twice the national average (27 percent versus 12 percent). In addition, the percentage of the population that is living below the poverty level (29 percent) and living below 2 times the poverty level (52 percent) is well above the national average (13 percent and 29 percent, respectively). Other demographics for the populations living within 5 km are below or near the respective national averages.

Within 50 km of the nine sources within the Integrated Iron and Steel Manufacturing Facilities category, the percent of the population that is African American is above the national average (20 percent versus 12 percent). Within 50 km the income demographics are similar to the national averages. Other demographics for the populations living within 50 km are below or near the respective national averages.

The methodology and the results of the demographic analysis are presented in the document titled *Analysis of Demographic Factors for Populations Living Near Integrated Iron and Steel Facilities,* which is available in the docket for this action.

As discussed in other subsections of the impacts of this action, in this action the EPA is proposing requirements for facilities to improve UFIP emission control resulting in reductions of both metal HAP and $PM_{2.5}$. We estimate that all facilities will achieve reductions of HAP emissions as a result of this proposed rule, including the facilities at which the percentage of the population living in close proximity who are African American and below poverty level is greater than the national average. The proposed changes will

[6] *https://www.epa.gov/environmentaljustice.*

[7] See *https://www.epa.gov/environmentaljustice/technical-guidance-assessing-environmental-justice-regulatory-analysis.*

have beneficial effects on air quality and public health for populations exposed to emissions from integrated iron and steel facilities.

TABLE 6—PROXIMITY DEMOGRAPHIC ASSESSMENT RESULTS FOR INTEGRATED IRON AND STEEL MANUFACTURING FACILITIES

Demographic group	Nationwide	Population within 50 km of 9 facilities	Population within 5 km of 9 facilities
Total Population	329,824,950	18,966,693	478,761
	Race and Ethnicity by Percent		
White	60	63	52
African American	12	20	27
Native American	0.6	0.1	0.2
Hispanic or Latino (includes white and nonwhite)	19	10	16
Other and Multiracial	9	7	5
	Income by Percent		
Below Poverty Level	13	13	29
Above Poverty Level	87	87	71
Below 2x Poverty Level	29	28	52
Above 2x Poverty Level	71	72	48
	Education by Percent		
Over 25 and without a High School Diploma	12	9	18
Over 25 and with a High School Diploma	88	91	82
	Linguistically Isolated by Percent		
Linguistically Isolated	5	3	6

Notes:

• The nationwide population count and all demographic percentages are based on the Census' 2016–2020 American Community Survey five-year block group averages and include Puerto Rico. Demographic percentages based on different averages may differ. The total population counts are based on the 2020 Decennial Census block populations.

• To avoid double counting, the ''Hispanic or Latino'' category is treated as a distinct demographic category for these analyses. A person is identified as one of five racial/ethnic categories above: White, African American, Native American, Other and Multiracial, or Hispanic/Latino. A person who identifies as Hispanic or Latino is counted as Hispanic/Latino for this analysis, regardless of what race this person may have also identified as in the Census.

In addition to the analyses described above, the EPA completed a risk-based demographics analysis for the residual risk and technology review (RTR) proposed rule (84 FR 42704, August 16, 2019) and the 2020 RTR final rule (85 FR 42074, July 13, 2020). A description of the demographic analyses and the results are provided in those two **Federal Register** documents.

VI. Request for Comments

We solicit comments on all aspects of this proposed action. In addition to general comments on this proposed action, we are also interested in receiving comments regarding the estimated emissions from UFIP sources, the estimated emissions reductions from the proposed measures, the proposed opacity limits and work practices, individually or together, to reduce emissions from the nonpoint sources, and the estimated costs to comply with the proposed requirements. EPA requests comment on the assumptions regarding the costs of capital, work practices, and emissions. EPA requests comment on the assumption that no additional facilities will close, open, or go idle over the time horizon set in our analysis. EPA acknowledges that other ongoing rulemaking efforts (including those affecting lime manufacturing, coke ovens, taconite iron ore processing, and electric arc furnace sources) may impact facilities in this source category and solicits comments on the cumulative regulatory burden of rules affecting these facilities. We solicit comments of how this proposed action interacts with potential timelines and changes to facilities installing carbon capture and/or using hydrogen or how the regulation might affect steel decarbonization efforts. We solicit comments on potential impacts, if any, on: U.S. manufacturing and supply chains; National Security; projects that use steel and iron for renewable and clean energy projects; aerospace manufacturing; telecommunications; critical infrastructure for national defense, and global competitiveness. We also solicit comment on the creation or retention of jobs and the quality of those jobs. We solicit comment on projects that use iron and steel that are funded by the Infrastructure Investment and Jobs Act (IIJA) (most commonly known as the Bipartisan Infrastructure Bill) and the CHIPS and Science Act.

VII. 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 13563 Improving Regulation and Regulatory Review

This action is a significant regulatory action that was submitted to OMB for review mainly because of the estimated benefits of the estimated $PM_{2.5}$ reductions described above. Any changes made in response to recommendations received as part of

Executive Order 12866 review have been documented in the docket.

B. Paperwork Reduction Act (PRA)

The information collection activities in this proposal have been submitted for approval to OMB under the PRA. The information collection request (ICR) document that the EPA prepared has been assigned EPA ICR number 2003.10. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

Respondents/affected entities: Integrated iron and steel manufacturing facilities.

Respondent's obligation to respond: Mandatory (40 CFR part 63, subpart FFFFF).

Estimated number of respondents: 8 facilities.

Frequency of response: One time.

Total estimated burden: The annual recordkeeping and reporting burden for facilities to comply with all of the requirements in the NESHAP is estimated to be 30,400 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: The annual recordkeeping and reporting cost for all facilities to comply with all of the requirements in the NESHAP is estimated to be $3,950,000 per year, of which $3,140,000 per year is for this proposal, and $803,000 is for other costs related to continued compliance with the NESHAP including $108,000 for paperwork associated with operation and maintenance requirements.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden to the EPA using the docket identified at the beginning of this rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov,* Attention: Desk Officer for the EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than August 30, 2023. The EPA will respond to any ICR-related comments in the final rule.

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 would not impose any requirements on small entities. No small entities are subject to the requirements of this rule.

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications as specified in Executive Order 13175. It will not have substantial direct effects on Tribal governments, 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. No Tribal governments own facilities subject to the NESHAP. Thus, Executive Order 13175 does not apply to this action.

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

Executive Order 13045 (62 FR 19885, April 23, 1997) directs Federal agencies to include an evaluation of the health and safety effects of the planned regulation on children in Federal health and safety standards and explain why the regulation is preferable to potentially effective and reasonably feasible alternatives. This action is not subject to Executive Order 13045 because the EPA does not believe the environmental health risks or safety risks addressed by this action present a disproportionate risk to children.

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

This action is not subject to Executive Order 13211, because it is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

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

This action involves technical standards. Therefore, the EPA conducted searches for the Integrated Iron and Steel Manufacturing Facilities NESHAP through the Enhanced National Standards Systems Network (NSSN) Database managed by the American National Standards Institute (ANSI). We also conducted voluntary consensus standards (VCS) organizations and accessed and searched their databases. We conducted searches for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 17, 23, 25A, 26A, 29, and 30B of 40 CFR part 60, appendix A, 320 of 40 CFR part 63 appendix, and SW–846 Method 9071B. During the EPA's VCS search, if the title or abstract (if provided) of the VCS described technical sampling and analytical procedures that are similar to the EPA's referenced method, the EPA ordered a copy of the standard and reviewed it as a potential equivalent method. We reviewed all potential standards to determine the practicality of the VCS for this rule. This review requires significant method validation data that meet the requirements of EPA Method 301 for accepting alternative methods or scientific, engineering, and policy equivalence to procedures in the EPA referenced methods. The EPA may reconsider determinations of impracticality when additional information is available for particular VCS.

No applicable VCS was identified for EPA Methods 1, 2, 2F, 2G, 3, 3A, 3B, 4, 5, 5D, 9, 17, 23, 25A, 26A, 29, 30B and SW–846 Method 9071B not already incorporated by reference in this subpart. The search identified one VCS that was potentially applicable for this rule in lieu of EPA Method 29. After reviewing the available standard, the EPA determined that the VCS identified for measuring emissions of pollutants subject to emissions standards in the rule would not be practical due to lack of equivalency. The EPA is incorporating by reference the VCS ASTM D6348–12(2020), ''Determination of Gaseous Compounds by Extractive Direct Interface Fourier Transform (FTIR) Spectroscopy''. The VCS ASTM D6348–12(2020) may be obtained from *https://www.astm.org* or from the ASTM Headquarters at 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, Pennsylvania 19428–2959. In the September 22, 2008, NTTA summary, ASTM D6348–03(2010) was determined equivalent to EPA Method 320 with caveats. ASTM D6348–12e1 is a revised

version of ASTM D6348–03(2010) and includes a new section on accepting the results from direct measurement of a certified spike gas cylinder, but still lacks the caveats we placed on the D6348–03(2010) version. The voluntary consensus standard ASTM D6348–12e1 has been reaffirmed and is now ASTM D6348–12(2020) and is an acceptable alternative to EPA Method 320 at this time with caveats requiring inclusion of selected annexes to the standard as mandatory. When using ASTM D6348–12(2020), the following conditions must be met:

(1) The test plan preparation and implementation in the Annexes to ASTM D 6348–12(2020), Sections A1 through A8 are mandatory; and

(2) In ASTM D6348–12(2020) Annex A5 (Analyte Spiking Technique), the percent (%) R must be determined for each target analyte (Equation A5.5). In order for the test data to be acceptable for a compound, %R must be 70% ≥ R ≤ 130%. If the %R value does not meet this criterion for a target compound, the test data is not acceptable for that compound and the test must be repeated for that analyte (*i.e.,* the sampling and/or analytical procedure should be adjusted before a retest). The %R value for each compound must be reported in the test report, and all field measurements must be corrected with the calculated %R value for that compound by using the following equation:

Reported Results = ((Measured Concentration in Stack))/(%R) × 100

The EPA is also incorporating by reference Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, Version 2.0 (Final), March 2008 (EPA–454/B–08–002). The Quality Assurance Handbook for Air Pollution Measurement Systems, Volume IV: Meteorological Measurements, Version 2.0 may be found at *https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100FOMB.TXT.*

Additional information for the VCS search and determination can be found in the memorandum, *Voluntary Consensus Standard Results for National Emission Standards for Hazardous Air Pollutants: Integrated Iron and Steel Manufacturing,* which is available in the docket for this action. The EPA welcomes comments on this aspect of the proposed rulemaking and, specifically, invites the public to identify potentially applicable VCS, and to explain why the EPA should use such standards in this regulation.

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

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on communities with EJ concerns. For this action the EPA conducted an assessment of the impacts that would result from the proposed rule amendments, if promulgated, on various demographic groups living near Integrated Iron and Steel facilities (as described in section V.C of this preamble).

The EPA believes that the human health or environmental conditions that exist prior to this action result in or have the potential to result in disproportionate and adverse human health or environmental effects on communities with EJ concerns. For populations living within 5 km of the nine integrated iron and steel facilities, the percent of the population that is African American is more than twice the national average (27 percent versus 12 percent). Specifically, the percent of the population that is African American is more than 1.5 times the national average within 5 km of six of the nine facilities. The percentage of the population that is living below the poverty level (29 percent) and living below 2 times the poverty level (52 percent) is well above the national average (13 percent and 29 percent, respectively). Specifically, the percent of the population that is living below the poverty level is more than 1.5 times the national average within 5 km of seven of the nine facilities. Other demographics for the populations living within 5 km are below or near the respective national averages.

The EPA believes that this action is likely to reduce existing disproportionate and adverse effects on communities with EJ concerns. This action requires facilities to improve UFIP emission control resulting in reductions of about 110 tpy of metal HAP and about 820 tpy $PM_{2.5}$. We estimate that all facilities will achieve reductions of HAP emissions as a result of this proposed rule, including the facilities at which the percentage of the population living in close proximity who are African American and below poverty level is greater than the national average.

The information supporting this Executive Order review is contained in sections IV and V of this preamble. The demographic analysis is available in a document titled *Analysis of Demographic Factors for Populations Living Near Integrated Iron and Steel Facilities,* which is available in the docket for this action.

Michael S. Regan,

Administrator.

[FR Doc. 2023–15085 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 0

[WT Docket No. 23–158; GN Docket No. 14–177; FCC 23–51; FR ID 157853]

Shared Use of the 42–42.5 GHz Band

AGENCY: Federal Communications Commission.

ACTION: Proposed rule; solicitation of comment.

SUMMARY: In this document, the Federal Communications Commission (Commission or FCC) seeks comment on how innovative, non-exclusive spectrum access models might be deployed in the 42 GHz band (42–42.5 GHz) to provide increased access to high-band spectrum, particularly by smaller wireless service providers, and to support efficient, intensive use of the band. The Commission also seeks comment on how potential sharing and licensing regimes might lower barriers to entry for smaller or emerging wireless service providers, encourage competition, and prevent spectrum warehousing.

DATES: Comments are due on or before August 30, 2023; reply comments are due on or before September 29, 2023. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public, the Office of Management and Budget (OMB), and other interested parties on or before September 29, 2023. Written comments on the Initial Regulatory Flexibility Analysis (IRFA) in this document must have a separate and distinct heading designating them as responses to the IRFA and must be submitted by the public on or before August 30, 2023.

ADDRESSES: Pursuant to §§ 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). You may submit comments, identified by WT Docket No. 23–158; and GN Docket 14–177, by any of the following methods:

• *Electronic Filers:* Comments may be filed electronically using the internet by accessing the ECFS: *http://apps.fcc.gov/ecfs/.*

• *Paper Filers:*

• Parties who choose to file by paper must file an original and one copy of each filing.

• Filings can be sent by commercial overnight courier, or by first-class or overnight U.S. Postal Service mall. 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.

• Effective March 19, 2020, and until further notice, the Commission no longer accepts any hand or messenger delivered filings. This is a temporary measure taken to help protect the health and safety of individuals, and to mitigate the transmission of COVID–19. *See FCC Announces Closure of FCC Headquarters Open Window and Change in Hand-Delivery Policy, Public Notice, DA 20–304 (March 19, 2020). https://www.fcc.gov/document/fcc-closes-headquarters-open-window-and-changes-hand-delivery-policy.*

People with Disabilities: To request materials in accessible formats (braille, large print, computer diskettes, or audio recordings), please send an email to *FCC504@fcc.gov* or call the Consumer & Government Affairs Bureau at (202) 418–0530 (VOICE), (202) 418–0432 (TTY).

FOR FURTHER INFORMATION CONTACT: *Catherine Schroeder* of the Wireless Telecommunications Bureau, Broadband Division, at *Catherine.Schroeder@fcc.gov* or 202–418–1956. For additional information concerning the Paperwork Reduction Act proposed information requirements contained in this document, send an email to *PRA@fcc.gov* or contact Kathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Notice of Proposed Rulemaking* (*NPRM)* in WT Docket No. 23–158 and GN Docket No. 14–177; FCC 23–51, adopted on June 8, 2023, and released on June 9, 2023. The full text of this document is available at *https://docs.fcc.gov/public/attachments/FCC-23-51A1.pdf.*

Regulatory Flexibility Act: The Regulatory Flexibility Act of 1980, as amended (RFA), requires an agency to prepare a regulatory flexibility analysis for notice-and-comment rulemakings, unless the agency certifies that ''the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities.'' The Commission seeks comment on potential rule and policy changes contained in the *NPRM,* and accordingly, has prepared an IRFA. The IRFA for this *NPRM* in WT Docket No. 23–158 and GN Docket No. 14–177 is set forth below in this document and written public comments are requested. Comments must be filed by the deadlines for comments on the *NPRM* indicated under the **DATES** section of this document and must have a separate and distinct heading designating them as responses to the IRFA. The Commission reminds commenters to file in the appropriate dockets: WT Docket No. 23–158 and GN Docket No. 14–177.

Paperwork Reduction Act: This document may contain proposed modified information collection requirements. Therefore, the Commission seeks comment on potential new or revised information collections subject to the Paperwork Reduction Act of 1995. If the Commission adopts any new or revised information collection requirements, the Commission will publish a notice in the **Federal Register** inviting the general public and the Office of Management and Budget to comment on the information collection requirements, as required by the Paperwork Reduction Act of 1995, Public Law 104–13. 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 comments on how it might further reduce the information collection burden for small business concerns with fewer than 25 employees.

Ex Parte Rules: This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's *ex parte* rules. 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. 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. In proceedings governed by rule 1.49(f) 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). 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 Rule 1.1206(b). Participants in this proceeding should familiarize themselves with the Commission's *ex parte* rules.

Synopsis

I. Notice of Proposed Rulemaking in WT Docket No. 23–158 and GN Docket No. 14–177

A. Background

1. As part of a multiyear effort to enable deployment of advanced wireless services such as 5G, the Commission has made 4.95 gigahertz of spectrum above 24 GHz available on an exclusively-licensed geographic area basis. The Commission has already established service and licensing rules for the 24 GHz, 28 GHz, Upper 37 GHz, 39 GHz, and 47 GHz bands, all of which are available on either a county or a Partial Economic Area (PEA) basis.[1] The

[1] *See Use of Spectrum Bands Above 24 GHz For Mobile Radio Services, et al.,* Report and Order and Further Notice of Proposed Rulemaking, 31 FCC Rcd 8014, 8154, paragraph 403 (2016); *Use of Spectrum Bands Above 24 GHz For Mobile Radio Services, et al.,* Second Report and Order, Second Further Notice of Proposed Rulemaking, Order on Reconsideration, and Memorandum Opinion and Order, 32 FCC Rcd 10988 (2017); *Use of Spectrum Bands Above 24 GHz For Mobile Radio Services, et al.,* Third Report and Order, Memorandum Opinion

Commission has held three auctions to award licenses in these bands, the most recent of which was completed in 2020.

2. The Commission also has made available a significant amount of high-band spectrum for unlicensed use. The rules for unlicensed device use at 57–64 GHz were expanded in 2016 to include 64–71 GHz, bringing the total amount of high-band spectrum available on an unlicensed basis to 14 gigahertz.

3. The 42 GHz band is currently allocated to non-Federal Fixed and Mobile services on a primary basis; there is no Federal allocation in the band.[2] Although the Commission sought comment previously on proposed service rules for this band among other bands above 24 GHz, none are currently in place, and the band has no incumbent licensees.[3] The lower adjacent 40–42 GHz band has been designated for satellite use. The upper adjacent 42.5–43.5 GHz band is allocated to radio astronomy services (RAS) on a primary basis for Federal and non-Federal use and to the Federal fixed, fixed-satellite (Earth-to-space), and mobile—except aeronautical mobile—services on a primary basis.[4]

4. The Commission previously sought comment on a proposal to authorize flexible fixed and mobile operations in the 42 GHz band under the new part 30 Upper Microwave Flexible Use Service (UMFUS) rules, but only on the condition that adjacent channel RAS at 42.5–43.5 GHz could be protected. Specifically, the Commission sought comment and detailed information on what protections should be established for this adjacent band—for example, whether out-of-band emission limits into the 42.5–43.5 GHz band should be established or whether it was necessary to create a guard band below 42.5 GHz. The Commission also sought comment on the appropriate band plan for the 42 GHz band, including whether the band should be licensed as a single channel, split into two channels, or split into multiple 100 megahertz channels. The Commission proposed licensing the band geographically using PEAs.

5. Pursuant to the directives in the MOBILE NOW Act,[5] the Commission later included in the *Third FNPRM,* 83 FR 34520 (July 20, 2018), requests for further comment on a regulatory framework to enable licensed and/or unlicensed uses of the 42 GHz band. The Commission received 17 comments and six reply comments to the *Third FNPRM* relating to the 42 GHz band.

B. Shared Use of the 42–42.5 GHz Band

1. Potential Benefits of Shared Licensing

6. Millimeter wave (mmW)[6] transmissions have a shorter propagation range than lower-frequency spectrum and are blocked by walls and other obstacles, making it easier to reuse the same band or channel within a smaller geographic area. Technological advances such as MIMO (multiple-input multiple-output) and beamforming antennas offer additional possibilities for reuse between multiple operators. Given that the Commission already has offered both traditionally-licensed spectrum (on a geographic basis) and made spectrum available on a flexible basis for unlicensed devices in the mmW bands, and that the characteristics of mmW spectrum lend themselves to sharing and reuse, the Commission seeks to explore how novel approaches to shared licensing may support increased efficiency and intensity of use among a wider range of users within this mmW spectrum.

7. Unlike many other mmW bands, the 42 GHz band has no existing operations, either federal or non-federal.[7] This ''greenfield'' spectrum gives the Commission greater flexibility in designing a shared licensing scheme that may be optimized for future use and can take advantage of new developments in technology more easily than a band with existing deployments. The Commission therefore believes that consideration of alternatives to exclusive geographic area licensing in the 42 GHz band is appropriate.

8. Although the Commission has previously sought comment on licensing the 42 GHz band on the same geographic area basis as the UMFUS bands such as the 37/39 GHz bands,[8] those two ranges are separated by the 40–42 GHz satellite-only band. This separation means that there appear to be fewer potential synergies to using the same licensing approach in both bands than if the two could be combined into a single continuous band.

9. The benefits of potential unlicensed use of the 42 GHz band also appear to be limited. No commenter previously supported making this band available on an unlicensed basis, and de Vries suggested that unlicensed use of the band would not provide adequate protection against harmful interference. This latter point is significant given the importance of protecting RAS operations in the adjacent 42.5–43.5 GHz band. Harmful interference from unlicensed devices would likely be more difficult to resolve, given the additional difficulty relative to licensed operations of identifying the specific interferer.

10. In light of these considerations, the Commission seeks comment on applying a shared approach to the 42 GHz band. The Commission asks commenters to enumerate the benefits or drawbacks of this approach, as compared with either an exclusive-use licensed[9] or unlicensed approach.

2. Shared Licensing Approaches

11. In this section, the Commission discusses a variety of potential approaches to licensing the 42 GHz band on a shared basis. These approaches may have different costs and benefits in different situations, and some may facilitate certain uses better than others. The Commission seeks comment on these approaches and on any alternatives that might better promote its goals of more efficient spectrum use and lower barriers to spectrum access compared with traditional exclusive-use licensing in this band.

12. *Nationwide non-exclusive licensing.* Under this approach,

and Order, and Third Further Notice of Proposed Rulemaking, 33 FCC Rcd. 5576 (2018); *Use of Spectrum Bands Above 24 GHz For Mobile Radio Services, et al.,* Fourth Report and Order, 33 FCC Rcd 12168 (2018). *See also* 47 CFR 30.4, 30.5. When citing to the *Report and Order* portions of the 2016 or 2018 documents, the Commission will refer to the *First R&O* or *Third R&O,* respectively. When citing to the *Memorandum Opinion and Order* portion of the 2018 document, the Commission will refer to the *MO&O.* When citing to the *Further Notice of Proposed Rulemaking* portion of the 2016 or 2018 document, the Commission will refer to the *First FNPRM* or *Third FNPRM,* respectively.

[2] 47 CFR 2.106.

[3] Nine experimental licenses are authorized for testing using this frequency range. Pursuant to the Commission's rules, operation of an experimental radio station is permitted only on the condition that harmful interference is not caused to licensees. If harmful interference to an established radio service occurs, upon becoming aware of such harmful interference the Experimental Radio Service licensee must immediately cease transmissions. *See* 47 CFR 5.84.

[4] 47 CFR 2.106. Footnote US211 urges applicants for airborne or space stations assignments in the 40.5–42.5 GHz band to take all practicable steps to protect radio astronomy observations in the 42.5–43.5 GHz band from harmful interference. 47 CFR 2.106 n.US211.

[5] MOBILE NOW Act, Public Law 115–141, Div. P, tit. VI, 132 Stat. 1097 (2018), § 604(a), (b)(1), (b)(2) (codified at 47 U.S.C. 1503) (requiring the Commission to publish a Notice of Proposed Rulemaking to consider service rules to authorize mobile or fixed terrestrial wireless operations, including for advanced mobile service operations, in the 42 GHz band).

[6] Generally, spectrum between 30 GHz and 300 GHz.

[7] As of March 31, 2023, nine experimental licenses are authorized for testing using this frequency range; however, as noted above, these licenses are issued on a noninterference basis. *See* 47 CFR 5.84.

[8] Some commenters supported this approach.

[9] The Commission notes that it has already established a record on an exclusive-use licensed approach for the 42 GHz band. *See Third FNPRM,* 33 FCC Rcd at 5599, paragraph 54.

currently in use in the 70/80/90 GHz bands, operators would first obtain a nationwide non-exclusive license from the Commission, and then coordinate specific deployment sites with a third-party database. This approach would likely require advance work in identifying and setting up a database administrator but could facilitate quick and efficient site registration once established. OTI, focusing on point-to-multipoint service, supports this licensing regime for the 42 GHz band (as well as for the Lower 37 GHz band), and it argues that such a system would reduce costs and facilitate entry and coexistence between licensees. Charter also supports this approach for the Lower 37 GHz band, in order to promote greater efficiency.

13. The Commission seeks comment on the potential use of this nationwide non-exclusive licensing approach for the 42 GHz band. Would this model best facilitate efficient use of this spectrum? Would it lower barriers to entry as compared with either traditional exclusive-use licensing, or the other shared licensing approaches discussed in this *NPRM*? Commenters advocating such an approach should also provide information regarding any limitations that should be placed on users. For example, should all licensees operating in a common area have access to the full 500 megahertz or only a portion to preserve the ability of other licensees to operate in that same area? Should there be limitations on the size of a service area that could be registered with a database to promote coexistence and enable access by other licensees? Should the Commission simply make the band available and require licensees to cooperate in the selection and use of frequencies in the band? What are the costs and benefits of taking this approach? The Commission notes that OTI's proposal focuses on fixed point-to-multipoint service. Would it be possible to use this approach to license mobile service as well? What would be the costs or obstacles associated with identifying and establishing a database administrator? The Commission seeks comment on these issues and any other considerations involved with a nationwide non-exclusive model for this band.

14. *Site-based licensing.* Alternatively, the Commission could license the 42 GHz band on a site-by-site basis directly, without the use of a nationwide non-exclusive license regime or a third-party database. This approach might provide greater transparency than the use of third-party databases, because information for each licensed site—including, for example, construction notifications demonstrating whether buildout requirements have been met—would be publicly available in the Commission's Universal Licensing System (ULS). This would also allow the Commission to be more responsive to potential disputes, and facilitate easier administration and enforcement of buildout requirements, without needing to communicate with the third-party database manager as part of this process.

15. The Commission seeks comment on a potential site-based licensing approach in this context. Would licensing each individual site directly be overly burdensome on licensees? Would adopting a site-based licensing approach facilitate the easier enforcement of buildout requirements as compared to using a third party database registrar, and therefore contribute to greater efficiency and less warehousing of this spectrum? To what extent would the lack of a third-party database administrator result in logistical hurdles that might increase costs or decrease efficiency of licensees' operations, or would it be a benefit to have license issues addressed directly with the Commission? Would prospective licensees be able to access this spectrum more quickly and easily under a third-party database approach, versus licensing each site with the Commission? Would there be additional or different technical or operational rules needed under either approach, for example specific rules for resolving coexistence issues under site-based licensing versus relying on the database for this purpose in a third-party registration approach? The Commission seeks comment on these and any other considerations relating to this licensing model.

16. *Technology-based sensing.* In the context of the Lower 37 GHz band, Qualcomm proposes that the Commission adopt a technology-based long-term sensing mechanism for mmW spectrum. Qualcomm suggests that this approach would allow ''multiple licensees each using any air interface, to share on a licensed basis the entire . . . band in the same location, on the same frequencies, and at the same time, by taking advantage of the highly directional nature of mmW communications.'' [10] This proposal, which describes technology-based sensing using a geographic area licensing regime, would require that licensees coordinate among themselves a measurement window during which all licensees (except for a priority user in each channel) cease transmissions for a given time period in order to use long-term sensing to detect any active receivers, and then transmit afterwards only in directions where no such receivers are detected. Qualcomm suggests that, if properly implemented, this system would provide priority licensees with more reliable protection than other sensing-based systems such as Listen Before Talk, and would also allow indoor operation across the entire band without disrupting priority or outdoor operations, and without requiring a database.

17. The Commission seeks comment on applying this potential approach to the 42 GHz band, and the attendant costs and benefits of adopting a technology-based sensing framework. Because Qualcomm designed this proposal for the Lower 37 GHz band, are there changes that would need to be made to make it suitable for the 42 GHz band? For example, would this proposal be viable without a priority user in a given channel? Similarly, given that Qualcomm's proposal demonstrates how technology-based sensing operates using geographic license areas, would adjustments need to be made to the proposal for a different type of licensing regime? Further, would the measurement and sensing requirements mean that users of the 42 GHz band could not take advantage of the equipment ecosystems of existing millimeter-wave bands? If so, would it increase equipment costs or increase barriers to entry for smaller or emerging operators? Are there other long-term sensing systems that should be considered? The Commission seeks comment on what steps the Commission or industry should take to ensure that, if adopted, any technology-based sensing protocols are non-proprietary/open-source or widely available to maximize use and drive innovation. The Commission seeks comment on these and any other considerations for this approach.

18. *Coordination mechanism.* The Commission assumes that any shared licensing regime will require a coordination mechanism to protect all licensees from harmful interference. Examples of potential coordination mechanisms include the third-party database queries used in 70/80/90 GHz, the Spectrum Access Systems (SAS) used in the Citizens Broadband Radio Service to manage access to spectrum by different classes of licensed users in the 3550–3700 MHz band, the Automated

[10] Letter from John W. Kuzin, Vice President, Qualcomm, to Marlene H. Dortch, Secretary, FCC, GN Docket 14–177 et al., at 1 (filed Mar. 18, 2022) (emphasis removed). *See also* Letter from John W. Kuzin, Vice President, Qualcomm, to Marlene H. Dortch, Secretary, FCC, GN Docket 14–177 et al., at 2 (filed Oct. 2, 2021).

Frequency Coordination (AFC) system recently established in 6 GHz to facilitate coexistence of unlicensed devices with incumbent operations and radio astronomy observatories, and equipment-based long-term sensing like the approach proposed by Qualcomm for the Lower 37 GHz band. The Commission seeks comment on these and other potential coordination mechanisms. What are the costs and benefits of each model? Which model would work best for each potential licensing regime? Are there concerns specific to the 42 GHz band that might recommend one coordination mechanism over another?

19. *Other Considerations.* The Commission seeks general comment on the sharing and licensing mechanisms described above, as applied to the 42 GHz band. Which model would be most conducive to the intensive and efficient use of this spectrum? Which model would yield the greatest benefits, at the least cost? What are the potential barriers to deployment, operation, or equipment availability under each model? The Commission also seeks comment on which types of services might be accommodated by these shared licensing regimes. OTI suggests the Commission also allow for point-to-multipoint service in this context. Would it be possible to accommodate both point-to-point and point-to-multipoint services in the 42 GHz band? Would it also be possible to accommodate mobile service? Are there specific licensing or sharing mechanisms that would better facilitate multiple services in the band? Are there specific technical or licensing requirements or coordination mechanisms that would better facilitate the inclusion of mobile service?

20. The Commission seeks comment on whether first-in-time protections [11] are necessary or appropriate for each of the shared licensing regimes discussed above, and if so, what form they should take. Charter argues that the use of time division duplex (TDD) synchronization would enable multiple operators to coexist in exactly the same area. Would requiring TDD synchronization be sufficient to enable such reuse? If so, would such a system render first-in-time protections moot? To what extent would the certainty provided by a first-in-time guarantee be necessary to encourage deployment in this band? Would the lack of such a guarantee deter investment by potential licensees? Do the answers to these questions depend on which shared licensing regime the Commission adopts? Are there licensing mechanisms (such as technology-based sensing) for which a first-in-time guarantee would be unnecessary, or more burdensome than beneficial? If the Commission does not adopt first-in-time protections, what other mechanisms might resolve situations of congestion or harmful interference in a particular area? The Commission seeks general comment on this issue, including on any other potential costs or benefits not mentioned here.

21. The Commission also seeks comment on the appropriate coordination requirements for site-based licensing or site-based registration (in conjunction with a nationwide license), should the Commission adopt it. OTI suggests that site-based licensing (or registration) should require coordination not only on a site-by-site basis, but on a sector-by-sector basis, to increase spectrum reuse, avoid warehousing, and encourage competition. Would this level of specificity be feasible from a deployment perspective? Would it be unduly burdensome on licensees who might wish to license or register multiple sectors at the same site? How prevalent are deployment scenarios in which operators use only a subset of sectors? Would access to one sector (or some subset of a full arc) at a particular site provide smaller or later-deploying operators with a greater opportunity to deploy alongside other licensees? If the Commission does incorporate sector-level licensing or registration, what would the appropriate sector size be? Is it 30-degree sectors, as OTI suggests? Should the Commission allow licensees or registrants to specify a sector size when applying or registering? If sector-based licensing is not appropriate in the 42 GHz band, is there some other way of licensing or registering sites that might facilitate greater spectrum reuse while still providing licensees with adequate spectrum access?

22. The Commission also seeks comment on whether there would be any potential synergies in the instant context with approaches being considered for the Lower 37 GHz (37–37.6 GHz) band. In 2016, the Commission adopted rules to permit fixed and mobile terrestrial operation across the 37 GHz band (37–38.6 GHz) and made the Lower 37 GHz band available for coordinated co-primary sharing between Federal and non-Federal users, with the non-Federal users licensed by rule. The Commission indicated that both Federal and non-Federal users would access the band by registering individual sites through a coordination mechanism and sought comment on the details of that coordination mechanism and what functions it should perform. In 2018, the Commission sought comment on several specific proposals for this coordination mechanism, including first-come-first-served site-based licensing or registration in conjunction with several different types of potential licenses. In addition to OTI, Charter, and Qualcomm, whose proposals are discussed above, several commenters suggest that Commission base its rules for Lower 37 GHz on those adopted for the 70/80 GHz bands. The Commission seeks comment on whether it should adopt a shared licensing approach for the 42 GHz band that mirrors the Commission's approach to the Lower 37 GHz band. What would be the benefits or costs to doing so? Are there other ways to leverage the potential of these bands together? The Commission notes that unlike the 42 GHz band, the Lower 37 GHz band must accommodate sharing and coordination between Federal and non-Federal users.

23. Finally, the Commission also seeks comment on any other model or mechanism for non-exclusive licensing not discussed here which may be better suited for the 42 GHz band, or any other relevant considerations for these or other shared licensing regimes. Commenters suggesting alternative approaches should do so with as much specificity as possible, including discussing the potential costs and benefits of their proposed option as compared with the approaches above and either an exclusive-use licensed or unlicensed approach. The Commission also seeks comment on whether it could enable secondary operations in the 42 GHz band, while still ensuring primary licensees protection from harmful interference.

3. Buildout Requirements

24. In traditional exclusive-use geographic area licensing regimes, the Commission typically sets buildout requirements in terms of service coverage of a given percentage of the population of the license area. For licensing regimes not tied to a particular license area, or where a license area is shared among multiple licensees, however, this metric may not be suitable or feasible. The Commission's overarching goal is to adopt a buildout metric that ensures in each circumstance that spectrum is meaningfully being put to use in practice. To this end, the Commission

[11] The Commission could, for example adopt a first-come-first-served licensing or registration scheme in which the first actual users that are licensed/registered have a right to interference protection (provided they deploy their systems within the requisite time period), but they have no right to exclude other users.

seeks comment on the appropriate buildout requirements for potential licensees under the various approaches described above.

25. One buildout approach could be to require licensees to begin operations within a specified time. OTI has proposed that an appropriate timeframe would be 12 months or less from site registration, after which a licensee would lose any first-in-time protections for that site. The Commission seeks comment on this proposal, including any alternative timeframes. The Commission also seeks comment on whether this approach would be better suited to certain sharing and licensing regimes, and, conversely, whether it might be unsuitable or inapplicable to certain others. Recognizing that the Commission seeks comment above on whether it should adopt first-in-time protections for this band, if the Commission ultimately do not adopt such protections as part of the shared licensing regime here, what other consequence for failing to meet a build-out deadline might be appropriate? Would any consequence for failure to build out in a timely manner be necessary in such circumstances?

26. The Commission also seeks general comment on the appropriate buildout metrics for potential technology-based sharing regimes. If the Commission ultimately adopts a sharing mechanism where the equipment itself determines access to spectrum, should it impose any buildout requirement at all, or is the inherently non-exclusive nature of such a regime sufficient to ensure efficient use and prevent spectrum warehousing? The Commission seeks comment on these and any other considerations for buildout requirements under sharing regimes based on technology-based long-term sensing, including any potential solutions not discussed here.

27. The Commission also seeks comment on any other potential buildout requirement metrics or levels suitable for the sharing mechanisms discussed in this *NPRM.* Additionally, to the extent that commenters have suggestions for other potential sharing or licensing mechanisms, the Commission encourages them to include suggestions for corresponding buildout requirements, or other methods of ensuring efficient spectrum use and preventing spectrum warehousing.

4. License Term and Applicability of Part 30 Technical Rules

28. The Commission previously sought comment on licensing the 42 GHz band under the part 30 UMFUS licensing and technical rules. Although the Commission is not proposing to adopt an exclusive-use licensing regime, it does propose to adopt a ten-year license term for licenses in this band, similar to other part 30 services. The Commission seeks comment on this proposal, and ask whether there are additional considerations in adopting a ten-year license term under a shared licensing approach.

29. The mmW bands the Commission has previously licensed are all governed by the technical rules found in part 30.[12] This uniform treatment facilitates development of a common equipment ecosystem and easier operator deployment, and is supported generally in the underlying record in this proceeding.[13] Inclusion in this uniform technical regime might allow these benefits to also accrue to the 42 GHz band. If this band is made available under a licensing scheme significantly different from the other part 30 bands, however, it is possible that those benefits might be diminished, or costs or other inefficiencies incurred.

30. The Commission seeks comment on the applicability of the part 30 technical rules to the 42 GHz band as licensed under the various potential sharing regimes outlined above. Should the Commission apply these existing technical rules for the 42 GHz band, regardless of the licensing regime it ultimately adopts? Are there changes to the technical rules might be appropriate or necessary to accommodate shared licensing? Are there different costs or benefits that may be associated with the existing part 30 technical rules in this context, which the Commission has not previously considered?

5. Band Plan

31. In the *Third FNPRM,* the Commission proposed to license the 42 GHz band as five 100 megahertz channels. Most commenters supported the Commission's proposal. They noted that a 100 megahertz channel is a building block for mmW mobile equipment, and that this channel size is consistent with 3rd Generation Partnership Project (''3GPP'') standards in the mmW bands. Several commenters also asserted that 100 megahertz block sizes would facilitate the deployment of 5G services. A few commenters advocated using 200 MHz channels. For example, TIA argues that wider channels will better support 5G services.[14] In response to the *First FNPRM,* 81 FR 58269 (August 24, 2016), Qualcomm also supported a band plan with two 200 megahertz channels.

32. The Commission again proposes to license the 42 GHz band in five 100 megahertz channels and seeks comment on this proposal in the context of the new proposals under consideration here. Would the benefits previously noted by commenters supportive of 100 megahertz channels still apply under the sharing regimes discussed above? Would the increased flexibility of a non-exclusive licensing regime benefit more from 100 megahertz channels, or from another channel size? Are there particular sharing or licensing regimes that would benefit most from a different channel size?

6. Protecting RAS Services at 42.5–43.5 GHz

33. As noted above, in the *First FNPRM,* the Commission proposed to authorize flexible mobile and fixed operations in the 42 GHz band, provided that RAS could be protected in the adjacent 42.5–43.5 GHz band.[15] The Commission sought comment on the forms that such protection should take, *e.g.,* whether it should establish special out-of-band emission (OOBE) limits into the 42.5–43.5 GHz band or create a guard band below 42.5 GHz. After noting the National Academy of Sciences' Committee on Radio Frequencies (CORF) and T-Mobile's agreement that RAS bands could be protected by limiting UMFUS operations near an RAS observatory, the Commission renewed its call in the *Third FNPRM* for interested parties to provide detailed technical analysis of the coexistence of RAS with terrestrial mobile operations that fully supported any proposed methodology. Specifically, the Commission asked whether its rules should be based on the International Telecommunication Union Radiocommunication Sector (ITU–R) RA.769 parameters, or alternate protection criteria, and sought comment on whether to establish coordination zones around relevant RAS facilities.

34. CORF has asserted that frequency lines at 42.519, 42.821, 43.122, and 43.424 GHz are of the greatest importance for the detection of strong silicon monoxide maser emissions from stars and star forming regions, which

[12] 47 CFR 30.201 through 209.

[13] No commenters oppose the inclusion of 42 GHz in these technical rules, or suggest specific variations.

[14] TIA addressed this issue in its comments to a separate Further Notice, 83 FR 42089 (Aug. 20, 2018). *See Use of Spectrum Bands Above 24 GHz For Mobile Radio Services,* GN Docket 14–177, *Fourth Further Notice of Proposed Rulemaking,* 33 FCC Rcd 7674 (2018) (*Fourth FNPRM*). *See* TIA *Fourth FNPRM* Comments at 5–6, Table 1, 11.

[15] The adjacent band, 42.5–43.5 GHz, is allocated for Federal and non-Federal RAS operations and Federal fixed, earth-to-space satellite and mobile services. 47 CFR 2.106.

facilitates the measurement of stellar temperature, density, wind velocity and other parameters. The 42 GHz band also is one of the preferred bands for measuring continuum observations. RAS observations are currently made at a limited set of observatories around the United States.[16] Additionally, according to a report by the National Academy of Sciences, Engineering, and Medicine, the Next Generation Very Large Array (ngVLA) is a top priority for U.S. astronomy in the coming decade and would include new sites predominantly near the current VLA, but also throughout New Mexico and adjacent states with long baseline stations in close proximity to existing VLBA stations. Because a typical radio telescope receives less than 1 percent of one-billionth of one-billionth of a watt (10^{-20} W) from a typical cosmic object, the telescope is particularly vulnerable to in-band emissions, spurious out-of-band emissions, and emissions producing harmonics, making protection important. CORF has represented that the detrimental levels for continuum and spectral line radio astronomy observations for single dishes are -227 dBW/m^2/Hz and -210 dBW/m^2/Hz, respectively, for the average across the full 1 gigahertz of the 42.5–43.5 GHz band and the peak level in any single 500 kHz channel, as based upon ITU–R RA.769, Tables 1 and 2, respectively. For observations using the entire VLBA, CORF represented that the corresponding limit is -175 dBW/m^2/Hz). T-Mobile agreed that the ITU power flux density (PFD) limits are appropriate to address potential interference to RAS.

35. Proponents of using the 42 GHz band for flexible terrestrial wireless use have generally agreed that various practical methods may be effective at protecting RAS, including use of exclusion zones, coordination zones, and aggregate emissions limits—particularly because RAS sites are remotely located. None provide detailed information or examples showing how these proposed methods would work in practice.[17] Regarding whether it is necessary or appropriate to establish a guard band below 42.5 GHz in order to protect RAS, CORF stated that a guard band of 200 MHz within the radio horizon around radio astronomy sites would meet the ITU–R RA.769 protection criteria. T-Mobile argued that a guard band is unnecessary and the ITU protection threshold can be met with minimum exclusion distances. In response to the *First FNPRM,* some commenters asserted that a guard band would narrow the usable aspects of the 42 GHz band.[18] TIA argued it should be possible to craft UMFUS operating rules that protect adjacent RAS services via geographic coordination or otherwise, making guard bands unnecessary, especially since they interfere with the Commission's channel block plans.

36. The Commission agrees with CORF and T-Mobile that RAS bands can probably be protected by limiting 42 GHz operations near a RAS facility to reduce the risk of terrestrial interference. Because the Commission believes that geographic separation of 42 GHz licensed operations and RAS facilities will provide sufficient protection of RAS facilities, it does not propose to impose out-of-band emissions limits on licenses in the 42 GHz band that are tighter than out-of-band-emissions limits on UMFUS licenses in other mmW bands. Furthermore, the Commission does not propose to establish coordination zones around RAS facilities because it believes that compliance with the limits it proposes in this *NPRM* will be sufficient to protect RAS observations. The record to date does not contain sufficient information to determine whether, and if so, at what distances, coordination zones would be appropriate, but the Commission invites the submission of such information from commenters.

37. The Commission proposes to require 42 GHz licensees to limit emissions into the 42.5–43.5 GHz passive band at those relatively few locations where RAS observatories make observations in this band. The Commission proposes to adopt the parameters established by ITU–R RA.769 as the interference protection criteria for RAS operations, as suggested by CORF and T-Mobile. While the Commission believes that these parameters are extremely conservative, no one has previously submitted studies suggesting alternative criteria, and the ITU's analysis indicates compliance with those criteria are likely to protect the RAS facilities from harmful interference. Given that the observatories are mostly located in remote areas and signals in this frequency range are significantly attenuated by terrain and clutter, the Commission expects that adopting these conservative criteria would have only a small impact on 42 GHz licensed operations.

38. Therefore, for all 42 GHz licensees operating near designated RAS facilities, the Commission proposes that: (1) the spectral PFD received at the RAS sites at the Haystack Observatory (Westford, MA), the Green Bank Telescope (Green Bank, WV) and the Very Large Array (Socorro, NM) averaged over the entire 42.5–43.5 GHz frequency range must not exceed -227 dBW/m^2/Hz; (2) the spectral PFD received within any 500 kHz channel within the 42.5–43.5 GHz frequency range for the three sites noted above must not exceed -210 dBW/m^2/Hz; and, (3) the spectral PFD within the 42.5–43.5 GHz frequency range for the Very Long Baseline Array (VLBA) Stations must not exceed -175 dBW/m^2/Hz. The Commission proposes to list the relevant sites in a new footnote to the United States Table of Frequency Allocations for clarity. The Commission believes that these limits are sufficient to protect RAS operations in the adjacent band without establishing a guard band within the 42 GHz band. The Commission emphasizes that its proposal to adopt these limits is based on the specific factors present in the 42 GHz band and would not necessarily control future decisions it makes regarding other frequency bands subject to note US342. In addition to these requirements, the existing requirements for coordination in the National Radio Quiet Zone will be maintained.[19] The Commission seeks comment on this proposal.

C. Costs and Benefits and Diversity, Equity, and Inclusion

39. The Commission invites comment generally on the costs and benefits associated with the various approaches discussed in this *NPRM.* Are there any aspects of the above issues that the Commission has not considered? Are there any studies, efforts, or analyses that the Commission should consider? If so, the Commission asks that commenters identify them and explain why they should be considered.

40. *Digital Equity and Inclusion.* Finally, the Commission, as part of its

[16] RAS observations in this band are currently made at various U.S. observatories: Green Bank Telescope (GBT), WV; VLA Socorro, NM; Westford, MA (Haystack); Brewster, WA; Fort Davis, TX; Hancock, NH; Kitt Peak, AZ; Los Alamos, NM; Mauna Kea, HI; North Liberty, IA; Owens Valley, CA; Pie Town, NM; St. Croix, VI. CORF FNPRM Comments at 9 & n.7 (*citing* 47 CFR 2.106, n.US131).

[17] Although they provide no new studies, Nokia and others direct the Commission to T-Mobile's RAS sharing study, produced for the 32/47/50 GHz bands and assert this study is well-suited to also calculating protection zones for RAS sites operating adjacent to the 42 GHz band. CORF agrees this study could be applicable for calculating coordination distances. The Commission does not find this study sufficient to establish coordination distances because it is based on an analysis done with respect to different systems in the 32 GHz band.

[18] FWCC urges that any guard band adopted should be limited to fixed-only operations subject to full fixed service frequency coordination to control emissions in the direction of RAS sites.

[19] 47 CFR 1.924.

continuing effort to advance digital equity for all,[20] 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 [21] and any potential benefits that may be associated with the various approaches and issues discussed herein. Specifically, the Commission seeks comment on how the various approaches that the Commission may consider may promote or inhibit advances in diversity, equity, inclusion, and accessibility, as well the scope of the Commission's relevant legal authority.

II. Initial Regulatory Flexibility Analysis in WT Docket No. 23–158 and GN Docket No. 14–177

41. As required by the Regulatory Flexibility Act of 1980, as amended (RFA),[22] the Commission has prepared this Initial Regulatory Flexibility Analysis (IRFA) of the possible significant economic impact on a substantial number of small entities by the policies and rules proposed in this *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 in 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).[23] In addition, the *NPRM* and IRFA (or summaries thereof) will be published in the **Federal Register**.[24]

A. Need for, and Objectives of, the Proposed Rules

42. In the *NPRM,* the Commission proposes to increase the Nation's supply of spectrum for mobile broadband by adopting rules for fixed and mobile services in the 42–42.5 GHz band. The Commission proposes to license this spectrum on a shared, non-exclusive basis. This additional spectrum for mobile use will help ensure that the speed, capacity, and ubiquity of the nation's wireless networks keeps pace with the skyrocketing demand for mobile service. It will also make possible new types of services for consumers and businesses. The Commission seeks comment on the specific types of licenses under which it should make this spectrum available, including non-exclusive nationwide licensing, site-based licensing, and technology-based sensing. The Commission seeks comment in particular on what licensing models might best facilitate entry and participation by smaller and emerging entities as well as comments that provide options for potentially lowering barriers to entry for smaller or emerging wireless service providers, encourage competition, and avoid spectrum warehousing.

43. Until recently, the mmW bands were generally considered unsuitable for mobile applications because of propagation losses at such high frequencies and the inability of mmW signals to propagate around obstacles. As increasing congestion has begun to fill the lower bands and carriers have resorted to smaller and smaller microcells in order to re-use the available spectrum, the industry is taking another look at the mmW bands and beginning to realize that at least some of the presumed disadvantages can be turned to advantages. For example, short transmission paths and high propagation losses can facilitate spectrum re-use in microcellular deployments by limiting the amount of interference between adjacent cells. Furthermore, where longer paths are desired, the extremely short wavelengths of mmW signals make it feasible for very small antennas to concentrate signals into highly focused beams with enough gain to overcome propagation losses. The short wavelengths of mmW signals also make it possible to build multi-element, dynamic beam-forming antennas that will be small enough to fit into handsets—a feat that might never be possible at the lower, longer-wavelength frequencies below 6 GHz where cell phones operate today.

B. Legal Basis

44. The proposed action is authorized pursuant to sections 1, 2, 4, 301, 302, 303, 304, 307, 309, and 310 of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154, 301, 302a, 303, 304, 307, and 309, § 604 of the MOBILE NOW Act, 47 U.S.C. 1503, and § 1.411 of the Commission's Rules, 47 CFR 1.411.

C. Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply

45. The RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted.[25] The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' [26] In addition, the term ''small business'' has the same meaning as the term ''small business concern'' under the Small Business Act.'' [27] A ''small business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.[28]

46. *Small Businesses, Small Organizations, Small Governmental Jurisdictions.* The Commission's actions, over time, may affect small entities that are not easily categorized at present. The Commission therefore describes here, at the outset, three broad groups of small entities that could be directly affected herein.[29] First, while there are industry specific size standards for small businesses that are used in the regulatory flexibility analysis, according to data from the SBA's Office of Advocacy, in general a small business is an independent business having fewer than 500 employees.[30] These types of small businesses represent 99.9% of all

[20] Section 1 of the Communications Act of 1934 as amended provides that the FCC ''regulat[es] interstate and foreign commerce in communication by wire and radio so as to make [such service] available, so far as possible, to all the people of the United States, without discrimination on the basis of race, color, religion, national origin, or sex.'' 47 U.S.C. 151.

[21] The term ''equity'' is used here consistent with E.O. 13985 as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ+) persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality. *See* E.O. 13985, 86 FR 7009, E.O. on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government (Jan. 20, 2021).

[22] *See* 5 U.S.C. 603. The RFA, 5 U.S.C. 601 through 612, has been amended by the Small Business Regulatory Enforcement Fairness Act of 1996, (SBREFA) Public Law 104–121, Title II, 110 Stat. 857 (1996).

[23] *See* 5 U.S.C. 603(a).

[24] *See id.*

[25] 5 U.S.C. 603(b)(3).

[26] 5 U.S.C. 601(6).

[27] 5 U.S.C. 601(3) (incorporating by reference the definition of ''small-business concern'' in the Small Business Act, 15 U.S.C. 632). Pursuant to 5 U.S.C. 601(3), the statutory definition of a small business applies ''unless an agency, after consultation with the Office of Advocacy of the Small Business Administration and after opportunity for public comment, establishes one or more definitions of such term which are appropriate to the activities of the agency and publishes such definition(s) in the **Federal Register**.''

[28] 15 U.S.C. 632.

[29] *See* 5 U.S.C. 601(3) through (6).

[30] *See* SBA, Office of Advocacy, Frequently Asked Questions, ''What is a small business?,'' *https://cdn.advocacy.sba.gov/wp-content/uploads/2021/11/03093005/Small-Business-FAQ-2021.pdf.* (Nov 2021).

businesses in the United States, which translates to 32.5 million businesses.[31]

47. Next, the type of small entity described as a ''small organization'' is generally ''any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' [32] The Internal Revenue Service (IRS) uses a revenue benchmark of $50,000 or less to delineate its annual electronic filing requirements for small exempt organizations.[33] Nationwide, for tax year 2020, there were approximately 447,689 small exempt organizations in the U.S. reporting revenues of $50,000 or less according to the registration and tax data for exempt organizations available from the IRS.[34] Finally, the small entity described as a ''small governmental jurisdiction'' is defined generally as ''governments of cities, counties, towns, townships, villages, school districts, or special districts, with a population of less than fifty thousand.'' [35] U.S. Census Bureau data from the 2017 Census of Governments [36] indicate there were 90,075 local governmental jurisdictions consisting of general purpose governments and special purpose governments in the United States.[37] Of this number, there were 36,931 general purpose governments (county,[38] municipal, and town or township [39]) with populations of less than 50,000 and 12,040 special purpose governments—independent school districts [40] with enrollment populations of less than 50,000.[41] Accordingly, based on the 2017 U.S. Census of Governments data, the Commission estimates that at least 48,971 entities fall into the category of ''small governmental jurisdictions.'' [42]

48. *Fixed Microwave Services.* Fixed microwave services include common carrier,[43] private-operational fixed,[44] and broadcast auxiliary radio services.[45] They also include the UMFUS,[46] Millimeter Wave Service (70/80/90 GHz),[47] Local Multipoint Distribution Service (LMDS),[48] the Digital Electronic Message Service (DEMS),[49] 24 GHz Service,[50] Multiple Address Systems (MAS),[51] and Multichannel Video Distribution and Data Service (MVDDS),[52] where in some bands licensees can choose between common carrier and non-common carrier status.[53] Wireless Telecommunications Carriers (*except* Satellite) [54] is the closest industry with a SBA small business size standard applicable to these services. The SBA small size standard for this industry classifies a business as small if it has 1,500 or fewer employees.[55] U.S. Census Bureau data for 2017 show that there were 2,893 firms that operated in this industry for the entire year.[56] Of this number, 2,837 firms employed fewer than 250 employees.[57] Thus under the SBA size standard, the Commission estimates that a majority of fixed microwave service licensees can be considered small.

49. The Commission's small business size standards with respect to fixed microwave services involve eligibility for bidding credits and installment payments in the auction of licenses for the various frequency bands included in fixed microwave services. When bidding credits are adopted for the auction of licenses in fixed microwave services frequency bands, such credits may be available to several types of small businesses based average gross revenues (small, very small and entrepreneur) pursuant to the competitive bidding rules adopted in conjunction with the requirements for the auction and/or as identified in part 101 of the Commission's rules for the

[31] *Id.*

[32] *See* 5 U.S.C. 601(4).

[33] The IRS benchmark is similar to the population of less than 50,000 benchmark in 5 U.S.C 601(5) that is used to define a small governmental jurisdiction. Therefore, the IRS benchmark has been used to estimate the number of small organizations in this small entity description. *See* Annual Electronic Filing Requirement for Small Exempt Organizations—Form 990–N (e-Postcard), ''Who must file,'' *https://www.irs.gov/charities-non-profits/annual-electronic-filing-requirement-for-small-exempt-organizations-form-990-n-e-postcard.* The Commission notes that the IRS data does not provide information on whether a small exempt organization is independently owned and operated or dominant in its field.

[34] *See* Exempt Organizations Business Master File Extract (E.O. BMF), ''CSV Files by Region,'' *https://www.irs.gov/charities-non-profits/exempt-organizations-business-master-file-extract-eo-bmf.* The IRS Exempt Organization Business Master File (E.O. BMF) Extract provides information on all registered tax-exempt/non-profit organizations. The data utilized for purposes of this description was extracted from the IRS E.O. BMF data for businesses for the tax year 2020 with revenue less than or equal to $50,000 for Region 1-Northeast Area (58,577), Region 2-Mid-Atlantic and Great Lakes Areas (175,272), and Region 3-Gulf Coast and Pacific Coast Areas (213,840) that includes the continental U.S., Alaska, and Hawaii. This data does not include information for Puerto Rico.

[35] *See* 5 U.S.C. 601(5).

[36] See 13 U.S.C. 161. The Census of Governments survey is conducted every five (5) years compiling data for years ending with ''2'' and ''7''. *See also* Census of Governments, *https://www.census.gov/programs-surveys/cog/about.html.*

[37] *See* U.S. Census Bureau, 2017 Census of Governments—Organization Table 2. Local Governments by Type and State: 2017 [CG1700ORG02], *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.* Local governmental jurisdictions are made up of general purpose governments (county, municipal and town or township) and special purpose governments (special districts and independent school districts). *See also* tbl.2. CG1700ORG02 Table Notes_Local Governments by Type and State_ 2017.

[38] *See id.* at Table 5. County Governments by Population-Size Group and State: 2017 [CG1700ORG05], *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.* There were 2,105 county governments with populations less than 50,000. This category does not include subcounty (municipal and township) governments.

[39] *See id.* at Table 6. Subcounty General-Purpose Governments by Population-Size Group and State: 2017 [CG1700ORG06], *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.* There were 18,729 municipal and 16,097 town and township governments with populations less than 50,000.

[40] *See id.* at Table 10. Elementary and Secondary School Systems by Enrollment-Size Group and State: 2017 [CG1700ORG10], *https://www.census.gov/data/tables/2017/econ/gus/2017-governments.html.* There were 12,040 independent school districts with enrollment populations less than 50,000. *See also* Table 4. Special-Purpose Local Governments by State Census Years 1942 to 2017 [CG1700ORG04], CG1700ORG04 Table Notes_ Special Purpose Local Governments by State_ Census Years 1942 to 2017.

[41] While the special purpose governments category also includes local special district governments, the 2017 Census of Governments data does not provide data aggregated based on population size for the special purpose governments category. Therefore, only data from independent school districts is included in the special purpose governments category.

[42] This total is derived from the sum of the number of general purpose governments (county, municipal and town or township) with populations of less than 50,000 (36,931) and the number of special purpose governments—independent school districts with enrollment populations of less than 50,000 (12,040), from the 2017 Census of Governments—Organizations Tables 5, 6 & 10.

[43] *See* 47 CFR part 101, subparts C and I.

[44] *See id.* Subparts C and H.

[45] Auxiliary Microwave Service is governed by part 74 of Title 47 of the Commission's Rules. *See* 47 CFR part 74. Available to licensees of broadcast stations and to broadcast and cable network entities, broadcast auxiliary microwave stations are used for relaying broadcast television signals from the studio to the transmitter, or between two points such as a main studio and an auxiliary studio. The service also includes mobile TV pickups, which relay signals from a remote location back to the studio.

[46] *See* 47 CFR part 30.

[47] *See* 47 CFR part 101, subpart Q.

[48] *See id.* Subpart L.

[49] *See id.* Subpart G.

[50] *See id.*

[51] *See id.* Subpart O.

[52] *See id.* Subpart P.

[53] *See* 47 CFR 101.533 and 101.1017.

[54] *See* U.S. Census Bureau, *2017 NAICS Definition, ''517312 Wireless Telecommunications Carriers* (*except Satellite*),'' *https://www.census.gov/naics/?input=517312&year=2017&details=517312.*

[55] *See* 13 CFR 121.201, NAICS Code 517312 (as of 10/1/22, NAICS Code 517112).

[56] *See* U.S. Census Bureau, *2017 Economic Census of the United States, Employment Size of Firms for the U.S.: 2017,* Table ID: EC1700SIZEEMPFIRM, NAICS Code 517312, *https://data.census.gov/cedsci/table?y=2017&n=517312&tid=ECNSIZE2017.EC1700SIZEEMPFIRM&hidePreview=false.*

[57] *Id.* The available U.S. Census Bureau data does not provide a more precise estimate of the number of firms that meet the SBA size standard.

specific fixed microwave services frequency bands.[58]

50. In frequency bands where licenses were subject to auction, the Commission notes that as a general matter, the number of winning bidders that qualify as small businesses at the close of an auction does not necessarily represent the number of small businesses currently in service. Further, the Commission does not generally track subsequent business size unless, in the context of assignments or transfers, unjust enrichment issues are implicated. Additionally, since the Commission does not collect data on the number of employees for licensees providing these services, at this time the Commission is not able to estimate the number of licensees with active licenses that would qualify as small under the SBA's small business size standard.

51. *Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing.* This industry comprises establishments primarily engaged in manufacturing radio and television broadcast and wireless communications equipment.[59] Examples of products made by these establishments are: transmitting and receiving antennas, cable television equipment, GPS equipment, pagers, cellular phones, mobile communications equipment, and radio and television studio and broadcasting equipment.[60] The SBA small business size standard for this industry classifies businesses having 1,250 employees or less as small.[61] U.S. Census Bureau data for 2017 show that there were 656 firms in this industry that operated for the entire year.[62] Of this number, 624 firms had fewer than 250 employees.[63] Thus, under the SBA size standard, the majority of firms in this industry can be considered small.

52. *Satellite Telecommunications.* This industry comprises firms ''primarily engaged in providing telecommunications services to other establishments in the telecommunications and broadcasting industries by forwarding and receiving communications signals via a system of satellites or reselling satellite telecommunications.'' [64] Satellite telecommunications service providers include satellite and earth station operators. The SBA small business size standard for this industry classifies a business with $38.5 million or less in annual receipts as small.[65] U.S. Census Bureau data for 2017 show that 275 firms in this industry operated for the entire year.[66] Of this number, 242 firms had revenue of less than $25 million.[67] Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 71 providers that reported they were engaged in the provision of satellite telecommunications services.[68] Of these providers, the Commission estimates that approximately 48 providers have 1,500 or fewer employees.[69] Consequently, using the SBA's small business size standard, a little more than half of these providers can be considered small entities.

53. *Wireless Telecommunications Carriers (except Satellite).* This industry comprises establishments engaged in operating and maintaining switching and transmission facilities to provide communications via the airwaves.[70] Establishments in this industry have spectrum licenses and provide services using that spectrum, such as cellular services, paging services, wireless internet access, and wireless video services.[71] The SBA size standard for this industry classifies a business as small if it has 1,500 or fewer employees.[72] U.S. Census Bureau data for 2017 show that there were 2,893 firms in this industry that operated for the entire year.[73] Of that number, 2,837 firms employed fewer than 250 employees.[74] Additionally, based on Commission data in the 2021 Universal Service Monitoring Report, as of December 31, 2020, there were 797 providers that reported they were engaged in the provision of wireless services.[75] Of these providers, the Commission estimates that 715 providers have 1,500 or fewer employees.[76] Consequently, using the SBA's small business size standard, most of these providers can be considered small entities.

54. *All Other Telecommunications.* This industry is comprised of establishments primarily engaged in providing specialized telecommunications services, such as satellite tracking, communications telemetry, and radar station operation.[77] This industry also includes establishments primarily engaged in providing satellite terminal stations and associated facilities connected with one or more terrestrial systems and capable of transmitting telecommunications to, and receiving telecommunications from, satellite systems.[78] Providers of internet services (*e.g.* dial-up ISPs) or Voice over internet Protocol (VoIP) services, via client-supplied telecommunications connections are also included in this industry.[79] The SBA small business size standard for this industry classifies firms with annual receipts of $35 million or less as small.[80] U.S. Census Bureau data for 2017 show that there were 1,079 firms in this industry that

[58] *See* 47 CFR 101.538(a)(1) through (3), 101.1112(b) through (d), 101.1319(a)(1) through (2), and 101.1429(a)(1) through (3).

[59] *See* U.S. Census Bureau, *2017 NAICS Definition, ''334220 Radio and Television Broadcasting and Wireless Communications Equipment Manufacturing,'' https://www.census.gov/naics/?input=334220&year=2017&details=334220.*

[60] *Id.*

[61] *See* 13 CFR 121.201, NAICS Code 334220.

[62] *See* U.S. Census Bureau, *2017 Economic Census of the United States, Employment Size of Firms for the U.S.: 2017,* Table ID: EC1700SIZEEMPFIRM, NAICS Code 334220, *https://data.census.gov/cedsci/table?y=2017&n=334220&tid=ECNSIZE2017.EC1700SIZEEMPFIRM&hidePreview=false.*

[63] *Id.* The available U.S. Census Bureau data does not provide a more precise estimate of the number of firms that meet the SBA size standard.

[64] *See* U.S. Census Bureau, *2017 NAICS Definition, ''517410 Satellite Telecommunications,'' https://www.census.gov/naics/?input=517410&year=2017&details=517410.*

[65] *See* 13 CFR 121.201, NAICS Code 517410.

[66] *See* U.S. Census Bureau, *2017 Economic Census of the United States, Selected Sectors: Sales, Value of Shipments, or Revenue Size of Firms for the U.S.: 2017,* Table ID: EC1700SIZEREVFIRM, NAICS Code 517410, *https://data.census.gov/cedsci/table?y=2017&n=517410&tid=ECNSIZE2017.EC1700SIZEREVFIRM&hidePreview=false.*

[67] *Id.* The available U.S. Census Bureau data does not provide a more precise estimate of the number of firms that meet the SBA size standard. The Commission also notes that according to the U.S. Census Bureau glossary, the terms receipts and revenues are used interchangeably, *see https://www.census.gov/glossary/#term_ReceiptsRevenueServices.*

[68] Federal-State Joint Board on Universal Service, Universal Service Monitoring Report at 26, Table 1.12 (2021), *https://docs.fcc.gov/public/attachments/DOC-379181A1.pdf.*

[69] *Id.*

[70] *See* U.S. Census Bureau, *2017 NAICS Definition, ''517312 Wireless Telecommunications Carriers (except Satellite),'' https://www.census.gov/naics/?input=517312&year=2017&details=517312.*

[71] *Id.*

[72] *See* 13 CFR 121.201, NAICS Code 517312 (as of 10/1/22, NAICS Code 517112).

[73] *See* U.S. Census Bureau, *2017 Economic Census of the United States, Employment Size of Firms for the U.S.: 2017,* Table ID: EC1700SIZEEMPFIRM, NAICS Code 517312, *https://data.census.gov/cedsci/table?y=2017&n=517312&tid=ECNSIZE2017.EC1700SIZEEMPFIRM&hidePreview=false.*

[74] *Id.* The available U.S. Census Bureau data does not provide a more precise estimate of the number of firms that meet the SBA size standard.

[75] Federal-State Joint Board on Universal Service, Universal Service Monitoring Report at 26, Table 1.12 (2021), *https://docs.fcc.gov/public/attachments/DOC-379181A1.pdf.*

[76] *Id.*

[77] *See* U.S. Census Bureau, *2017 NAICS Definition, ''517919 All Other Telecommunications,'' https://www.census.gov/naics/?input=517919&year=2017&details=517919.*

[78] *Id.*

[79] *Id.*

[80] *See* 13 CFR 121.201, NAICS Code 517919 (as of 10/1/22, NAICS Code 517810).

operated for the entire year.[81] Of those firms, 1,039 had revenue of less than $25 million.[82] Based on this data, the Commission estimates that the majority of ''All Other Telecommunications'' firms can be considered small.

D. Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities

55. The Commission expects the proposed rules in the *NPRM* will impose new or additional reporting or recordkeeping and/or other compliance obligations on small entities as well as other licensees and applicants. At this time however, the Commission is not in a position to determine whether, if adopted, its proposals and the matters upon which it seeks comment will require small entities to hire professionals to comply and cannot quantify the cost of compliance with the potential rule changes discussed herein.

56. Depending on the licensing model the Commission ultimately adopts for the 42 GHz band, applicants for licenses may be required to coordinate their proposed operations with other licensees and applicants. Under the relevant licensing models, such coordination would be necessary to ensure that neighboring operations will not interfere with each other. The Commission seeks comment on the cost to small entities for this potential coordination with operations.

57. Small entities and other applicants in the 42 GHz band may be required to meet buildout requirements. Depending on the type of buildout requirement the Commission ultimately adopts, licensees may be required to provide information to the Commission on the facilities they have constructed, the nature of the service they are providing, and the extent to which they are providing coverage in their license or registered site area. Any performance or buildout requirements the Commission adopts will be structured to ensure that spectrum is being put into use and to encourage rapid deployment of next generation wireless services, including 5G, which would benefit small entities and the industry as a whole. The Commission seeks comment as to the potential equipment, operational and implementation costs to small entities working towards complying with these buildout requirements.

E. Steps Taken To Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered

58. The RFA requires an agency to describe any significant, specifically small business, 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 such small entities.'' [83]

59. The Commission believes the potential licensing models on which it seeks comment would facilitate access to spectrum by small businesses and a wide variety of other entities. However, to assist in the Commission's evaluation of the economic impact on small entities as a result of actions that have been proposed in the *NPRM,* and to better explore options and alternatives, the Commission has sought comment from the parties. Of particular interest are those comments providing insight as to whether any of the costs associated with any potential performance or buildout requirements can be alleviated for small businesses. The Commission expects to more fully consider the economic impact and alternatives for small entities following the review of comments filed in response to the *NPRM.*

F. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Rules

60. None.

III. Ordering Clauses

61. Accordingly, *it is ordered,* pursuant to sections 1, 2, 4, 301, 302, 303, 304, 307, 309, and 310 of the Communications Act of 1934, 47 U.S.C. 151, 152, 154, 301, 302a, 303, 304, 307, and 309, § 604 of the MOBILE NOW Act, 47 U.S.C. 1503, and § 1.411 of the Commission's Rules, 47 CFR 1.411, that this *Notice of Proposed Rulemaking is hereby adopted.*

62. *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.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–16167 Filed 7–28–23; 8:45 am]

BILLING CODE 6712–01–P

[81] *See* U.S. Census Bureau, *2017 Economic Census of the United States, Selected Sectors: Sales, Value of Shipments, or Revenue Size of Firms for the U.S.: 2017,* Table ID: EC1700SIZEREVFIRM, NAICS Code 517919, *https://data.census.gov/cedsci/table?y=2017&n=517919&tid=ECNSIZE2017.EC1700SIZEREVFIRM&hidePreview=false.*

[82] *Id.* The available U.S. Census Bureau data does not provide a more precise estimate of the number of firms that meet the SBA size standard. The Commission also notes that according to the U.S. Census Bureau glossary, the terms receipts and revenues are used interchangeably, *see https://www.census.gov/glossary/#term_ReceiptsRevenueServices.*

[83] 5 U.S.C. 603(a)(1) through (4).

Notices

Federal Register

Vol. 88, No. 145

Monday, July 31, 2023

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 30, 2023 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food and Nutrition Service

Title: FNS–380–1, Supplemental Nutrition Assistance Program's Quality Control Review Schedule.

OMB Control Number: 0584–0299.

Summary of Collection: The FNS–380–1, Quality Control Review Schedule (QCRS), was developed by the Food and Nutrition Service (FNS) for State use to collect both QC data and case characteristics for SNAP and to serve as the comprehensive data entry form for SNAP QC reviews. The legislative basis for the QC system is in Section 16 of the Food and Nutrition Act of 2008, as amended (the Act). Part 275, subpart C, of SNAP regulations implements the legislative mandates found in Section 16. The regulatory basis for the QC reporting requirements is provided by 7 CFR 275.14(d) and 7 CFR 275.21. State agencies are required to perform QC reviews for SNAP.

Need and Use of the Information: The information needed to complete the FNS–380–1 form is obtained from the SNAP case record through State agency quality control findings. The information is used to monitor and reduce errors, develop policy strategies, and analyze household characteristic data.

Description of Respondents: State, Local and Tribal Governments.

Number of Respondents: 53.

Frequency of Responses: Reporting: Monthly.

Total Burden Hours: 49,291.

Food and Nutrition Service

Title: Food Program Reporting System (FPRS).

OMB Control Number: 0584–0594.

Summary of Collection: The Food and Nutrition Service (FNS) is consolidating certain programmatic and financial data reporting requirements under the Food Programs Reporting System (FPRS), an electronic reporting system. The purpose is to give State agencies, Business and Indian Tribal Organization (ITO) agencies one portal for the various reporting required for the programs that the State and ITO agencies operate.

Need and Use of the Information: The data collected will be used for a variety of purposes, mainly program evaluation, planning, audits, funding, research, regulatory compliance, and general statistics. The data is gathered at various times, ranging from monthly, quarterly, annual, or final submissions. Without the information, FNS would be unable to meet its legislative and regulatory reporting requirements for the affected programs.

Description of Respondents: State, Local or Tribal Government; Business.

Number of Respondents: 14,329.

Frequency of Responses: Reporting: Quarterly, Semi-annually, Monthly; Annually.

Total Burden Hours: 121,438.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–16127 Filed 7–28–23; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF AGRICULTURE

Forest Service

Malheur, Umatilla, and Wallowa-Whitman National Forests; Oregon and Washington; Revision of Land Management Plan for the Blue Mountains Forests

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of intent to initiate the assessment phase of the land management plan revision for the Malheur, Umatilla, and Wallowa-Whitman National Forests.

SUMMARY: The Forest Service, U.S. Department of Agriculture, is initiating the Land Management Plan revision process for the Malheur, Umatilla, and Wallowa-Whitman National Forests (Blue Mountains Forests), located in northeast Oregon and southeast Washington. This process will result in three revised Land Management Plans to guide all resource management activities on the Blue Mountains Forests for approximately fifteen years. This notice announces the initiation of the assessment phase, the preliminary stage of the plan revision process. Assessments will identify and consider relevant and readily accessible material about ecological, social, and economic conditions and trends in the planning area, including best available scientific information. Findings will be documented in an assessment report. Trends and conditions identified in the assessment will help describe a need to change the existing plans and inform

the revision of the three Land Management Plans.

DATES: The public will be invited to review the draft assessment and participate in this phase of the revision in the fall of 2023. Engagement opportunities will be posted on the Blue Mountains Forest Plan Revision website: *https://www.fs.usda.gov/detail/umatilla/home/?cid=fseprd1066821.* Consultation with the Tribes will also be conducted as part of the assessment phase of the revision. Information will be shared through mailing lists, social media, and other media outlets. The draft assessment is anticipated for public review and comment in fall 2023 and will be announced in the newspapers of record for the Malheur, Umatilla, and Wallowa-Whitman National Forests. The Forest Service will review and incorporate public comments and additional information from tribal consultation on the draft assessment and produce a final assessment to inform plan revision. The Forest Service may then initiate procedures pursuant to the National Environmental Policy Act (NEPA) to prepare revised Land Management Plans.

ADDRESSES: For questions about Land Management Plan revision or comments on initiating the assessment phase of plan revision, please address mail to: Umatilla National Forest, Attn: Darcy Weseman—Blues Forest Plan Revision, 72510 Coyote Rd., Pendleton, OR 97801 or via email to *sm.fs.bluesforests@usda.gov.* The majority of the revision team is located at the Umatilla National Forest Headquarters (72510 Coyote Rd., Pendleton, OR 97801); however, all three locations can provide information as requested: Malheur National Forest located at 431 Patterson Bridge Rd., John Day, OR 97845 and Wallowa-Whitman National Forest located at 1550 Dewey Avenue, Suite A, Baker City, Oregon 97814.

FOR FURTHER INFORMATION CONTACT: Michael Neuenschwander, Revision Team Leader at *michael.neuenschwander@usda.gov* or by phone 509–703–7525. Individuals who use telecommunication devices for the deaf and hard of hearing (TDD) may call the Federal Information Relay Service (FIRS) at 800–877–8339, 24 hours a day, every day of the year, including holidays.

SUPPLEMENTARY INFORMATION: The National Forest Management Act (NFMA) of 1976 requires that the Forest Service develop a Land Management Plan (Plan), for every national forest. Each National Forest and Grassland in the United States is governed by a Plan in accordance with the NFMA. Plans set desired conditions, standards, and guidelines for management, protection, and use of the Forest.

The Malheur, Umatilla, and Wallowa-Whitman Land Management Plans provide management direction for approximately 5.5 million acres of public lands and working forests under Forest Service management in northeastern Oregon and southeastern Washington. The Forest Service began efforts to revise the Plans in 2004, with the goal of replacing the existing Plans that took effect in 1990. Updating the Land Management Plans is important for providing a framework to address current economic, social, and ecological conditions in and around the Blue Mountains area. Multiple uses provided by the National Forest, including livestock grazing, timber harvest, forest recreation, tourism, and subsistence activities, are all important to economic and social life in the Blue Mountains area. The Forest Service previously attempted to revise the Blue Mountains Land Management Plans with a highly contentious planning effort that spanned 15 years. Ultimately, the Forest Service withdrew the Blue Mountains Revised Land Management Plans and Final Environmental Impact Statement in March 2019, before the plans were finalized and implemented. Afterward, Forest Service leadership from the Pacific Northwest Regional Office and the Malheur, Umatilla, and Wallowa-Whitman National Forests met with the Eastern Oregon Counties Association to better understand concerns and identify opportunities to approach forest planning and management in a new way. The participants recognized the need to work together at a larger scale, which included working with other government entities within and surrounding the Blue Mountains geographic area that were most impacted by the Plans. The various government entities officially formed the Blues Intergovernmental Council (BIC) in November 2019, to develop joint recommendations on the most contentious issues identified in the Blue Mountains Land Management Plan Revision process. These recommendations will serve as a baseline to be further informed by public engagement, as well as tribal and agency consultation, throughout the plan revision process.

The Forest Service is reinitiating Land Management Plan revision under the 2012 planning rule, which will include robust external engagement opportunities throughout the entire process. Using the 2012 planning rule, each Forest Supervisor will sign a separate decision for their respective National Forest's revised Plan. This approach enhances opportunities for local engagement and contributions because the decisions will be made at the local level.

This notice announces the start of the first stage of the process, during which updated information from the public, Tribes, other government agencies, and non-governmental parties will be compiled into an assessment. Information relevant to the assessment includes the status and trends of ecological, social, and economic conditions within the planning area and across the broader landscape. The planning rule requires the responsible official to identify and evaluate existing conditions and trends for 15 topic areas during the assessment (36 CFR 219.6(b); *https://www.ecfr.gov/current/title-36/chapter-II/part-219/subpart-A/section-219.6*).

During this assessment phase, the Forest Service invites other government agencies, Tribes, non-governmental parties, and the public to share information about social, economic, and environmental conditions of the Blue Mountains Forests and the broader landscape. Existing information about conditions of the three National Forests, supplemented with information gathered through public engagement and tribal consultation, will be integrated into final resource assessments. The Forest Service will host public outreach forums to share progress and gather additional information. To have a successful public participation process, the Forest Service will incorporate methods and tools that provide a spectrum of opportunities for the public to engage throughout the Land Management Plan Revision process. The Forest Service will implement actions that foster community building and are transparent, timely, inclusive, interactive, respectful, and efficient. The resulting Blue Mountains National Forests' Plans will provide for ecosystem services and multiple uses through sustainable, integrated resource management.

Responsible Officials: There will be three responsible officials, one for each forest. The responsible official for the Land Management Plans are Ann Niesen, Malheur Forest Supervisor; Eric Watrud, Umatilla Forest Supervisor; and Shaun McKinney Wallowa-Whitman Forest Supervisor.

Dated: July 26, 2023.

Troy Heithecker,

Associate Deputy Chief, National Forest System.

[FR Doc. 2023–16162 Filed 7–28–23; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Commonwealth of the Northern Mariana Islands Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement 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 Commonwealth of the Northern Mariana Islands Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a briefing at 9:00 a.m. ChST on Friday, September 1, 2023, (7:00 p.m. ET on Thursday, August 31, 2023) in Pod Y–10 at the Northern Marianas College (Finasisu Lane, Saipan, Northern Mariana Islands 96950). The purpose of the meeting is to hear testimony on the accessibility and quality of healthcare in the CNMI judicial system.

DATES: Friday, September 1, 2023, from 9 a.m.–5 p.m. ChST (Thursday, August 31, 2023, from 7 p.m.–3 a.m. ET).

ADDRESSES: Northern Marianas College, Finasisu Lane, Saipan, Northern Mariana Islands 96950; Pod Y–10.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Any interested member of the public may attend this committee 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. To request accommodations, please email Liliana Schiller, Support Services Specialist, at *lschiller@usccr.gov* at least10 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 Kayla Fajota at *kfajota@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, 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, Commonwealth of the Northern Mariana Islands 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. Introductory Remarks
III. Panelist Presentations & Committee Q&A
IV. Public Comment
V. Closing Remarks
VI. Adjournment

Dated: July 25, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–16092 Filed 7–28–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Guam Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Announcement 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 Guam Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a business meeting at 9:00 a.m. ChST on Wednesday, August 30, 2023, (7:00 p.m. ET on Tuesday, August 29, 2023) in the Anthony Leon Guerrero Multipurpose Room at the University of Guam (32 University Drive, Mangilao, Guam 96913). The purpose of the meeting is to collect input from members of the public on potential civil rights topics of study for the Committee's investigation.

DATES: Wednesday, August 30, 2023, from 9 a.m.–11 a.m. ChST (Tuesday, August 29, 2023, from 7 p.m.–9 p.m. ET).

ADDRESSES: University of Guam, 32 University Drive, Mangilao, Guam 96913; Anthony Leon Guerrero Multipurpose Room.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota, DFO, at *kfajota@usccr.gov* or (434) 515–2395.

SUPPLEMENTARY INFORMATION: Any interested member of the public may attend this committee 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. To request accommodations, please email Liliana Schiller, Support Services Specialist, at *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 Kayla Fajota at *kfajota@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, 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, Guam 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. Introductory Remarks
III. Public Comment
IV. Committee Discussion
V. Next Steps
VI. Adjournment

Dated: July 25, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–16091 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–23–2023]

Foreign-Trade Zone (FTZ) 136; Authorization of Production Activity; Airbus OneWeb Satellites, North America LLC; (Satellites and Satellite Systems); Merritt Island, Florida

On March 28, 2023, Airbus OneWeb Satellites, North America LLC submitted a notification of proposed production activity to the FTZ Board for its facility within FTZ 136 in Merritt Island, Florida.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 19908, April 4, 2023). On July 26, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: July 26, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–16206 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–560–826]

Monosodium Glutamate From the Republic of Indonesia: 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 sales of monosodium glutamate (MSG) from the Republic of Indonesia (Indonesia) have been made below normal value during the period of review (POR), November 1, 2021, through October 31, 2022. We invite interested parties to comment on these preliminary results.

DATES: Applicable July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4261.

SUPPLEMENTARY INFORMATION:

Background

Commerce is conducting an administrative review of the antidumping duty order on MSG from Indonesia covering two respondents: PT. Cheil Jedang Indonesia (CJ Indonesia) and PT. Miwon Indonesia (PT. Miwon).[1] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[2]

Scope of the Order [3]

The merchandise covered by this *Order* is MSG, whether or not blended or in solution with other products. Specifically, MSG that has been blended or is in solution with other product(s) is included in the *Order* when the resulting mix contains 15 percent or more of MSG by dry weight. Products with which MSG may be blended include, but are not limited to, salts, sugars, starches, maltodextrins, and various seasonings. Further, MSG is included in the *Order* regardless of physical form (including, but not limited to, in monohydrate or anhydrous form, or as substrates, solutions, dry powders of any particle size, or unfinished forms such as MSG slurry), end-use application, or packaging. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Because CJ Indonesia and PT. Miwon failed to cooperate to the best of their abilities in responding to our requests for information, we relied on facts available, with adverse inferences, in determining these companies' dumping margins, consistent with section 776 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an appendix to this notice. The Preliminary Decision Memorandum 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 our review, we preliminarily determine the following weighted-average dumping margins exist for the period November 1, 2021, through October 31, 2022:

Manufacturer/exporter	Weighted-average dumping margin (percent)
PT. Cheil Jedang Indonesia	* 58.67
PT. Daesang Ingredients Indonesia and PT. Miwon Indonesia [4]	* 58.67

* Rate based on adverse facts available (AFA).

Disclosure and Public Comment

As the dumping margins in this review were based on AFA, there are no calculations to release to parties in this review. Interested parties are invited to comment on the preliminary results of this review. Pursuant to 19 CFR 351.309(c)(1)(ii), interested parties may submit case briefs not later than 30 days after the date of publication of this notice in the **Federal Register**. Rebuttal briefs, limited to issues raised in the case briefs, may be filed later than seven

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 88 FR 50, 52 (January 3, 2023). On August 26, 2022, Commerce published the final results of a changed circumstances review of MSG from Indonesia. Commerce found that PT. Daesang Ingredients Indonesia (PT. Daesang) is the successor-in-interest to PT. Miwon. *See Monosodium Glutamate from the Republic of Indonesia: Final Results of Changed Circumstances Review,* 87 FR 52506 (August 26, 2022) (*MSG from Indonesia CCR*). Because the effective date of this decision was during the POR, we continue to reference the respondent here as PT. Miwon.

[2] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Monosodium Glutamate from the Republic of Indonesia; 2021–2022'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[3] *See Monosodium Glutamate from the People's Republic of China, and the Republic of Indonesia: Antidumping Duty Orders; and Monosodium Glutamate from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value,* 79 FR 70505 (November 26, 2014) (*Order*).

[4] As noted above, on August 26, 2022, Commerce published the final results of a changed circumstances review of MSG from Indonesia. Commerce found that PT. Daesang is the successor-in-interest to PT. Miwon. *See MSG from Indonesia CCR.* Cash deposits of estimated antidumping duties required pursuant to the final results of this review will be applied to PT. Daesang. Liquidation instructions for the POR will be issued for PT Daesang/PT. Miwon.

days after the date for filing case briefs.[5] Parties who submit case briefs or rebuttal briefs in this review are requested to submit with each brief: (1) a statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[6] Case and rebuttal briefs should be filed using ACCESS and must be served on interested parties.[7] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8]

Pursuant to 19 CFR 351.310(c), any interested party may request a hearing within 30 days of the publication of this notice in the **Federal Register**. If a hearing is requested, Commerce will notify interested parties of the hearing schedule. Interested parties who wish to request a hearing, or to participate if one is requested, must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs.

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[9] If the weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), then Commerce will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). If the weighted-average dumping margin is zero or *de minimis* in the final results, or if an importer-specific assessment rate is zero or *de minimis* in the final results, Commerce will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of subject merchandise covered by the final results of this review, where applicable.

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 MSG from Indonesia entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 6.19 percent, the all-others rate established in the investigation.[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of our analysis of issues raised by the parties in the written comments, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) 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

These preliminary results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Application of Facts Available and Use of Adverse Inferences
V. Recommendation

[FR Doc. 2023–16090 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–831]

Prestressed Concrete Steel Wire Strand From Mexico: Initiation of Circumvention Inquiry on the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In response to a request from Insteel Wire Products Company, Sumiden Wire Products Corporation, and Wire Mesh Corp. (collectively, the requestors), the U.S. Department of Commerce (Commerce) is initiating a country-wide circumvention inquiry to determine whether imports of certain high carbon steel (HCS) wire from Mexico that are assembled or completed into prestressed concrete steel wire strand (PC strand) in the United States, are circumventing the antidumping duty order on PC strand from Mexico.

DATES: Applicable July 31, 2023.

---

[5] *See* 19 CFR 351.309(d); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020) (''To provide adequate time for release of case briefs via ACCESS, E&C intends to schedule the due date for all rebuttal briefs to be 7 days after case briefs are filed (while these modifications remain in effect).'').

[6] *See* 19 CFR 351.309(c)(2), (d)(2).

[7] *See* 19 CFR 351.303 (for general filing requirements).

[8] *See* 19 CFR 351.303(f).

[9] *See* 19 CFR 351.212(b).

[10] *See Order.*

FOR FURTHER INFORMATION CONTACT: Craig Matney or Jonathan Schueler, Office VIII, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2429 and (202) 482–9175, respectively.

SUPPLEMENTARY INFORMATION:

Background

On June 9, 2023, pursuant to section 781(a) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.226(c), the requestors filed a circumvention inquiry request alleging that imports of HCS wire manufactured in Mexico and completed into PC strand in the United States are circumventing the antidumping duty order on PC strand from Mexico [1] and, accordingly, should be included within the scope of the *Order.*[2]

Scope of the Order

The merchandise covered by this *Order* is PC strand. Merchandise covered by the *Order* is currently classifiable under subheadings 7312.10.3010 and 7312.10.3012 of the Harmonized Tariff Schedule of the United States (HTSUS). While the HTSUS subheading and are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive. For a complete description of the scope, *see* the attachment to the Initiation Checklist.[3]

Merchandise Subject to the Circumvention Inquiry

This circumvention inquiry covers HCS wire imported from Mexico. The HCS wire has a high carbon content (*i.e.,* 0.78–0.85 percent), is not heat treated, and has a diameter less than 4.50 millimeters. The HCS wire is assembled or completed in the United States by stranding the HCS wire to produce PC strand of the type that would be subject to the *Order.*

Initiation of Circumvention Inquiry

Section 351.226(d) of Commerce's regulations states that if Commerce determines that a request for a circumvention inquiry satisfies the requirements of 19 CFR 351.226(c), then Commerce ''will accept the request and initiate a circumvention inquiry.'' Section 351.226(c)(1) of Commerce's regulations requires that each request for a circumvention inquiry allege ''the elements necessary for a circumvention determination under section 781 of the Act exist'' and be ''accompanied by information reasonably available to the interested party supporting these allegations.'' The requestors alleged circumvention pursuant to section 781(a) of the Act (merchandise completed or assembled in the United States).

According to section 781(a)(1) of the Act, after taking into account any advice provided by the U.S. International Trade Commission (ITC) under section 781(e) of the Act, Commerce may find the imported parts or components referred to in subparagraph (B) that are used in the completion or assembly of the merchandise in the United States to be covered by the scope of an order if: (A) merchandise sold in the United States is of the same class or kind as any merchandise produced in a foreign country that is the subject of an antidumping duty order or finding or a countervailing duty order; (B) such merchandise sold in the United States is completed or assembled in the United States from parts or components produced in the foreign country with respect to which such order or finding applies; (C) the process of assembly or completion in the United States referred to in subparagraph (B) is minor or insignificant; and (D) the value of the parts or components referred to in subparagraph (B) is a significant portion of the total value of the merchandise.

In determining whether the process of assembly or completion in the United States is minor or insignificant under section 781(a)(1)(C) of the Act, section 781(a)(2) of the Act directs Commerce to consider: (A) the level of investment in the United States; (B) the level of research and development in the United States; (C) the nature of the production process in the United States; (D) the extent of production facilities in the United States; and (E) whether the value of processing performed in the United States represents a small proportion of the value of the merchandise sold in the United States.

In addition, section 781(a)(3) of the Act sets forth additional factors to consider in determining whether to include merchandise assembled or completed in the United States within the scope of an antidumping or countervailing duty order. Specifically, Commerce shall take into account such factors as: (A) the pattern of trade, including sourcing patterns; (B) whether the manufacturer or exporter of the parts or components is affiliated with the person who assembles or completes the merchandise sold in the United States from the parts or components produced in the foreign country to which the order applies; and (C) whether imports into the United States of the parts or components produced in such foreign country have increased after the initiation of the investigation which resulted in the issuance of such order or finding.

Based on our analysis of the requestors' circumvention inquiry request, we determine that the requestors satisfied the criteria under 19 CFR 351.226(c), and thus, pursuant to 19 CFR 351.226(d)(1)(ii), we have accepted the request and are initiating the requested circumvention inquiry of the *Order.* For a full discussion of the basis for our decision to initiate the requested circumvention inquiry, *see* the Initiation Checklist. Moreover, as explained in the Initiation Checklist, we are initiating a country-wide circumvention inquiry. Commerce has taken this approach in prior circumvention inquiries where the facts warranted initiation on a country-wide basis.[4]

Consistent with the approach taken in prior circumvention inquiries that Commerce initiated on a country-wide basis, we intend to solicit information from producers and exporters in Mexico concerning shipments of Mexican HCS wire to the United States to be stranded into PC strand in the United States. A company's failure to completely respond to Commerce's requests for information may result in the application of partial or total facts available, pursuant to section 776(a) of the Act, which may include adverse inferences, pursuant to section 776(b) of the Act.

[1] *See Notice of Antidumping Duty Order: Prestressed Concrete Steel Wire Strand from Mexico,* 69 FR 4112 (January 28, 2004) (*Order*).

[2] *See* Requestors' Letter, ''Prestressed Concrete Steel Wire Strand From Mexico—Petitioners' Request for Circumvention Ruling Pursuant to Section 781(a), as Amended,'' dated June 9, 2023 (Circumvention Inquiry Request).

[3] *See* Checklist, ''Initiation of the Circumvention Inquiry on the Antidumping Duty Order,'' dated concurrently with, and hereby adopted by, this notice (Initiation Checklist), at Attachment.

[4] *See, e.g., Certain Corrosion-Resistant Steel Products from the Republic of Korea and Taiwan: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 83 FR 37785 (August 2, 2018); *Carbon Steel Butt-Weld Pipe Fittings from the People's Republic of China: Initiation of Anti-Circumvention Inquiry on the Antidumping Duty Order,* 82 FR 40556, 40560 (August 25, 2017) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted); and *Certain Corrosion-Resistant Steel Products from the People's Republic of China: Initiation of Anti-Circumvention Inquiries on the Antidumping Duty and Countervailing Duty Orders,* 81 FR 79454, 79458 (November 14, 2016) (stating at initiation that Commerce would evaluate the extent to which a country-wide finding applicable to all exports might be warranted).

Suspension of Liquidation

Pursuant to 19 CFR 351.226(l)(1), Commerce will notify U.S. Customs and Border Protection (CBP) of its initiation of the requested circumvention inquiry and direct CBP to continue the suspension of liquidation of entries of products subject to the circumvention inquiry that were already subject to the suspension of liquidation and to apply the cash deposit rate that would be applicable if the products were determined to be covered by the scope of the *Order.* Should Commerce issue a preliminary or final circumvention determination, Commerce will follow the suspension of liquidation rules under 19 CFR 351.226(l)(2)-(4).

Notification to Interested Parties

In accordance with 19 CFR 351.226(d) and section 781(a) of the Act, Commerce has determined that the requestors' request for a circumvention inquiry satisfies the requirements of 19 CFR 351.226(c). Accordingly, Commerce is notifying all interested parties of the initiation of a circumvention inquiry to determine whether U.S. imports of HCS wire, which are imported from Mexico and produced into PC strand and sold in the United States, are circumventing the *Order.* A description of the products that are subject to the circumvention inquiry, and an explanation of the reasons for Commerce's decision to initiate this inquiry, are included in the accompanying Initiation Checklist. In accordance with 19 CFR 351.226(e)(1), Commerce intends to issue its preliminary determination in this circumvention inquiry no later than 150 days from the date of publication of this notice in the **Federal Register**.

This notice is published in accordance with section 781(a) of the Act and 19 CFR 351.226(d)(1)(ii).

Dated: July 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2023–16089 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[C–580–879]

Certain Corrosion-Resistant Steel Products From the Republic of Korea: Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review, 2021

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to producers and exporters of certain corrosion-resistant steel products (CORE) from the Republic of Korea (Korea). The period of review (POR) is January 1, 2021, through December 31, 2021. Additionally, Commerce intends to rescind the review with respect to four companies.

DATES: Applicable July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Janae Martin or Zachariah Hall, 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) 482–0238 or (202) 482–6261, respectively.

SUPPLEMENTARY INFORMATION:

Background

Between July 21 and August 1, 2022, we received multiple requests for administrative review [1] of the countervailing duty order on CORE from Korea.[2] On September 6, 2022, Commerce published a notice of initiation of an administrative review of the *Order.* On October 20, 2022, Commerce selected KG Dongbu Steel Co., Ltd. (KG Dongbu) and Hyundai Steel Company as mandatory respondents in this administrative review. On March 16, 2023, Commerce extended the deadline for the preliminary results of this review.[3]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4] A list of topics discussed in the Preliminary Decision Memorandum is included at the Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx/.*

Scope of the Order

The merchandise covered by the *Order* is certain corrosion-resistant steel products. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Preliminary Intent To Rescind Administrative Review, in Part

Based on our analysis of U.S. Customs and Border Protection (CBP) data, we preliminarily determine that four companies, SeAH Steel Corporation, POSCO International, POSCO Steeleon, and Hyundai Steel Co., Ltd. had no reviewable shipments, sales, or entries of subject merchandise during the POR.

Absent any comments to the contrary from interested parties, pursuant to 19 CFR 351.213(d)(3), we intend to rescind the administrative review of these companies in the final results of review. For further information, *see* ''Preliminary Intent to Rescind Administrative Review, in Part'' in the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found countervailable, we preliminarily determine that there is a subsidy, *i.e.,* a financial contribution from an authority that gives rise to a

[1] *See* Hyundai Steel's Letter, ''Request for Administrative Review,'' dated July 21, 2022; *see also* POSCO, POSCO International, POSCO C&C, and POSCO Steeleon's Letter, ''Request for Administrative Review,'' dated July 27, 2022; *see also* KG Dongbu Steel's Letter, ''Request for Administrative Review,'' dated July 27, 2022; *see also* Petitioners' Letter, ''Request for Administrative Review,'' dated July 29, 2022; *see also* SeAH CM's and SeAH's Letter, ''Request for Administrative Review,'' dated August 1, 2022.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 54463 (September 6, 2022) (*Initiation Notice*); *see also Initiation of Antidumping and Countervailing Duty Administrative Reviews, 87 FR 61278 (October 11, 2022); see also Certain Corrosion-Resistant Steel Products from India, Italy Republic of Korea and the People's Republic of China: Countervailing Duty Order,* 81 FR 48387 (July 25, 2016) (*Order*).

[3] *See* Memorandum, ''Extension of Deadline for the Preliminary Results of the 2021 Countervailing Duty Administrative Review,'' dated March 16, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results and Partial Rescission of the Countervailing Duty Administrative Review; 2021: Certain Corrosion-Resistant Steel Products from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

benefit to the recipient, and that the subsidy is specific.[5] For a full description of the methodology underlying our conclusions, *see* the accompanying Preliminary Decision Memorandum.

Preliminary Rate for Non-Selected Companies Under Review

The statute and Commerce's regulations do not directly address the countervailing duty rates to be applied to companies not selected for individual examination where Commerce limited 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 states that for companies not investigated, in general, we will determine an all-others rate by weight-averaging the countervailable subsidy rates established for each of the companies individually investigated, excluding zero and *de minimis* rates or any rates based solely on the facts available.

Because the rates for KG Dongbu Steel and Hyundai Steel are above *de minimis* and not based entirely on facts available, we applied a subsidy rate to the non-selected companies under review based on a weighted average of the subsidy rates calculated for these mandatory respondents using the publicly ranged sales data they submitted on the record.

Preliminary Results of Review

As a result of this review, we preliminarily determine the net countervailable subsidy rates to be:

Producer/exporter	Subsidy rate (percent *ad valorem*)
KG Dongbu Steel Co., Ltd	6.71
Hyundai Steel Company[6]	0.59
POSCO	1.43
POSCO Coated and Color Steel Co., Ltd	1.43
SeAH Coated Metal	1.43

[5] *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.

Disclosure and Public Comment

We intend to disclose to interested parties the calculations performed for these preliminary results within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit written comments (case briefs) within 30 days of publication of the preliminary results and rebuttal comments (rebuttal briefs) within seven days after the time limit for filing case briefs.[7] Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[8] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this review 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.

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 submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice. Requests should contain the party's name, address, and telephone number, the number of participants, whether any participant is a foreign national, and 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 the date, time, and location of the hearing two days before the scheduled date.

Unless the deadline is extended, we intend to issue the final results of this administrative review, which will include the results of our analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rate

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producer/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, and CBP shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies for which this review is rescinded, we 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 the period January 1, 2021, through December 31, 2021, in accordance with 19 CFR 351.212(c)(l)(i). We intend to issue assessment instructions to CBP for these companies no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**.

For the companies remaining in the review, we will instruct CBP to assess countervailing duties on all appropriate entries at the subsidy rates calculated in the final results of this review. We intend 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

In accordance with 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 respective companies 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, we will instruct CBP to continue to collect cash deposits at the most recent company-specific or all others rate applicable to the company. These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results are issued and published pursuant to sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

[6] We note that Hyundai Steel and Hyundai Steel Company were treated as being minor variations of the same name at respondent selection. *See* Memorandum, ''Respondent Selection,'' dated October 20, 2022, at Attachment.

[7] *See* 19 CFR 351.309(c) and (d).

[8] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

Dated: July 25, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Preliminary Intent to Rescind Administrative Review, In Part
IV. Scope of the *Order*
V. Diversification of Korea's Economy
VI. Subsidies Valuation Information
VII. Analysis of Programs
VIII. Recommendation

[FR Doc. 2023–16200 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–423–813]

Citric Acid and Certain Citrate Salts From Belgium: 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) is conducting an administrative review of the antidumping duty (AD) order on citric acid and certain citrate salts (citric acid) from Belgium. We preliminarily determine that Citribel nv. (Citribel), formerly S.A. Citrique Belge N.V. (Citrique Belge), sold subject merchandise in the United States at prices below normal value during the July 1, 2021, through June 30, 2022, period of review (POR). We invite interested parties to comment on these preliminary results.

DATES: Applicable July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Deborah Cohen, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4521.

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2018, Commerce published the AD order on citric acid from Belgium in the **Federal Register**.[1] On September 6, 2022, pursuant to section 751(a)(1) of the Tariff Act of 1930, as amended (the Act), Commerce initiated an AD administrative review of the *Order* with respect to one company, Citribel.[2] During the course of this administrative review, Citribel responded to Commerce's questionnaire and supplemental questionnaires. On March 1, 2023, Commerce extended the deadline for issuing the preliminary results of this review to July 28, 2023.[3] For further details, *see* the accompanying Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise covered by this *Order* includes all grades and granulation sizes of citric acid, sodium citrate, and potassium citrate in their unblended forms, whether dry or in solution, and regardless of packaging type. For a full description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Act. Commerce calculated export price in accordance with section 772(a) of the Act and normal value in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. *See* the appendix to this notice for a complete list of the topics discussed in the Preliminary Decision Memorandum. 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 at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Preliminary Results of the Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the period July 1, 2021, through June 30, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Citribel nv	8.22

Disclosure and Public Comment

Commerce intends to disclose to interested parties the calculations performed for these preliminary results within five days of the date of publication of this notice.[5] Interested parties may submit case briefs no later than 30 days after the date of publication of these preliminary results of review in the **Federal Register**.[6] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[7] Parties who submit case or rebuttal briefs in this proceeding 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.[8] Executive summaries should be limited to five pages total, including footnotes. Case and rebuttal briefs should be filed using ACCESS. Note that Commerce has temporarily modified certain portions of its requirements for serving documents containing business proprietary information, until further notice.[9]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed request must be received successfully in its entirely by 5:00 p.m. Eastern Time within 30 days of the date of publication of this notice in the **Federal Register**.[10] Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3)

---

[1] *See Citric Acid and Certain Citrate Salts from Belgium, Colombia and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 54463 (September 6, 2022). Immediately prior to the initiation of this review, on July 29, 2022, Commerce completed a changed circumstances review, in which we determined that Citribel nv. is the successor-in-interest to S.A. Citrique Belge N.V., the sole respondent in all prior administrative reviews and the investigation of the *Order.* As a result, Citribel nv. is accorded the same AD cash deposit treatment as Citrique Belge with respect to subject merchandise. *See Citric Acid and Certain Citrate Salts from Belgium: Final Results of Antidumping Duty Changed Circumstances Review,* 87 FR 45750 (July 29, 2022) (*Citric Acid Belgium CCR*). As this name change occurred during the period of review and, thus, entries subject to this administrative review were made using both company names, both company names were listed in the *Initiation Notice.* Nevertheless, S.A. Citrique Belge N.V. and Citribel nv. represent the same respondent entity.

[3] *See* Memorandum, ''Extension of Deadline for Preliminary Results,'' dated March 1, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review: Citric Acid and Certain Citrate Salts from Belgium; 2020–2021,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] *See* 19 CFR 351.224(b).

[6] *See* 19 CFR 351.309(c)(1)(ii).

[7] *See* 19 CFR 351.309(d); *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); *see also* 19 CFR 351.303 (for general filing requirements).

[9] *See Temporary Rule.*

[10] *See* 19 CFR 351.310(c).

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.[11] Parties should confirm the date, time and location of the hearing by telephone two days before the scheduled date.

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised in any the written briefs, no later than 120 days after the date of publication of this notice, unless otherwise extended.[12]

Assessment Rates

Upon issuance of the final results of this administrative review, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries. If the weighted-average dumping margin for Citribel (*i.e.,* the sole individually-examined respondent in this review) is not zero or *de minimis* (*i.e.,* greater than or equal to 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates for the merchandise based on the ratio of the total amount of dumping calculated for the examined sales made during the POR to each importer and the total entered value of those same sales, in accordance with 19 CFR 351.212(b)(1).[13] Where an importer-specific *ad valorem* assessment rate is zero or *de minimis* in the final results of the review, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[14] If Citribel's weighted-average dumping margin is zero or *de minimis* in the final results of the review, we will instruct CBP not to assess duties on any of its entries in accordance with the *Final Modification for Reviews, i.e.,* ''{w}here the weighted-average margin of dumping for the exporter is determined to be zero or *de minimis,* no antidumping duties will be assessed.'' [15]

For entries of subject merchandise during the POR produced by Citribel for which the producer did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate (*i.e.,* 19.30 percent) [16] if there is no rate for the intermediate company (or companies) involved in the transaction.[17]

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 upon publication of the final results of this administrative review 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 Citribel will be equal to the weighted-average dumping margin established in the final results of this administrative review, except if the rate is less than 0.50 percent, and therefore *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, a prior review, or in the investigation but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be the all-others rate of 19.30 percent, the rate established in the less-than-fair-value investigation of this proceeding.[18] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 24, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Duty Absorption
V. Application of Facts Available and Use of Adverse Inferences
VI. Discussion of the Methodology
VII. Currency Conversion
VIII. Recommendation

[FR Doc. 2023–16201 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–874]

Certain Steel Nails From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review, Preliminary Determination of No Shipments, and Partial Rescission 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 certain steel nails (steel nails) from the Republic of Korea (Korea) were sold in the United States at less than normal value (NV) during the period of review (POR) of July 1, 2021, through June 30, 2022. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 31, 2023.

---

[11] *See* 19 CFR 351.310(d).

[12] *See* section 751(a)(3)(A) of the Act; and 19 CFR 351.213(h).

[13] As explained above, we determined that Citribel is the successor-in-interest to Citrique Belge. *See Citric Acid Belgium CCR.* This name change occurred during the period of review; thus, entries subject to this administrative review were made using both company names. Accordingly, we intend to issue assessment instructions covering entries produced and exported by both Citrique Belge and Citribel during the POR at the rate established in the final results.

[14] *See* 19 CFR 351.106(c)(2).

[15] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8102 (February 14, 2012) (*Final Modification for Reviews*).

[16] *See Order,* 83 FR at 35215.

[17] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[18] *See Order,* 83 FR at 35215.

FOR FURTHER INFORMATION CONTACT: Ashley Cossaart or Paul Gill, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0462 or (202) 482–5673, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 13, 2015, Commerce published in the **Federal Register** an antidumping duty order on steel nails from Korea.[1] On September 6, 2022, based on a timely request for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the *Order* covering 121 producers and/or exporters of the subject merchandise.[2] On March 9, 2023, Commerce extended the preliminary results of this review to no later than July 28, 2023.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

Scope of the Order

The merchandise subject to the *Order* is steel nails from Korea. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Partial Rescission of Administrative Review

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if a party who requested the review withdraws the request within 90 days of the date of publication of the notice of initiation of the requested review. On September 21, 2022, the petitioner[5] timely withdrew its request for Nailtech Co., Ltd. (Nailtech).[6] Because the request for administrative review of Nailtech was timely withdrawn, and no other parties requested a review of this company, Commerce is rescinding this review with respect to Nailtech.

Preliminary Determination of No Shipments

Among the companies under review, Astrotech Steels Private Limited (Astrotech) and Geekay Wires Limited (Geekay) properly filed statements that they made no shipments of subject merchandise to the United States during the POR.[7] Based on their certifications and our analysis of U.S. Customs and Border Protection (CBP) information, we preliminary determine that Astrotech and Geekay had no reviewable transactions during the POR.[8] Consistent with our practice, we are not preliminarily rescinding the review with respect to these companies. Instead, we will complete the review and issue appropriate instructions to CBP based on the final results of this review.[9]

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). We calculated export price in accordance with section 772 of the Act. We calculated NV 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 Appendix I 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 margins exist for the period July 1, 2021, through June 30, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
Daejin Steel Company	0.66
Korea Wire Co., Ltd	0.00
Companies Not Selected for Individual Review[10]	0.66

Review-Specific Rate for Companies Not Selected for Individual Review

The Act and Commerce's regulations do not address the establishment of a weighted-average dumping margin to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in a less-than-fair-value (LTFV) investigation, for guidance when calculating the weighted-average dumping margin 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 equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually examined, excluding any margins that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available.

For these preliminary results, because the rate calculated for Korea Wire Co., Ltd. (KOWIRE) is zero, we have preliminarily assigned a dumping margin to these companies based on the rate calculated for Daejin Steel Company (Daejin).

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.[11] Interested parties may submit case briefs to Commerce no later than 30 days after

[1] *See Certain Steel Nails from the Republic of Korea, Malaysia, the Sultanate of Oman, Taiwan, and the Socialist Republic of Vietnam: Antidumping Duty Orders,* 80 FR 39994 (July 13, 2015) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 87 FR 54463 (September 6, 2022).

[3] *See* Memorandum, ''Certain Steel Nails from the Republic of Korea: Extension of Deadline for Preliminary Results of 2021–2022 Antidumping Duty Administrative Review,'' dated March 9, 2023.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the 2021–2022 Administrative Review of the Antidumping Duty Order on Certain Steel Nails from the Republic of Korea,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[5] The petitioner is Mid Continent Steel & Wire, Inc.

[6] *See* Petitioner's Letter, ''Certain Steel Nails from Korea—Withdrawal of Review Request,'' dated September 21, 2022.

[7] *See* Geekay's Letter, ''Certain Steel Nails—Republic of Korea: Request for No Shipment during the Period of Review (POR),'' dated September 21, 2022; *see* also Astrotech's Letter, ''Certain Steel Nails from Republic of Korea—Request for No Shipment during the Period of Review (POR),'' dated September 29, 2022.

[8] *See* Memorandum, ''No Shipment Inquiry for Astrotech Steels Private Limited and Geekay Wires Limited during the period 07/01/2021 through 06/30/2022,'' dated July 20, 2023.

[9] *See, e.g., Welded Line Pipe from the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020,* 87 FR 928 (January 7, 2022), unchanged in *Welded Line Pipe from the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2019–2020,* 87 FR 38061 (June 27, 2022).

[10] The exporters and/or producers not selected for individual review are listed in Appendix II.

[11] *See* 19 CFR 351.224(b).

the date of publication of this notice.[12] 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.[13] 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.[14] Case and rebuttal briefs should be filed using ACCESS.[15]

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.[16] 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. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, parties will be notified of the time and date for the hearing.[17]

An electronically-filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time on the established deadline. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[18]

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 in the **Federal Register**, unless otherwise extended.[19]

Assessment Rates

Upon completion of the administrative review, Commerce shall determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[20] Pursuant to 19 CFR 351.212(b)(1), because both respondents reported the entered value for all of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of antidumping duties calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce's ''automatic assessment'' will apply to entries of subject merchandise during the POR produced by Daejin or KOWIRE for which these 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.[21]

For the companies which were not selected for individual review, we will assign an assessment rate based on the review-specific rate, calculated as noted in the ''Review-Specific Rate for Companies Not Selected for Individual Review'' section, above. Further, if we continue to find in the final results that Astrotech and Geekay had no shipments of subject merchandise during the POR, we will instruct CBP to liquidate any suspended entries that entered under these companies' antidumping duty case numbers at the all-others rate.

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.[22]

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 companies 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 covered by this review, the cash deposit 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 LTFV investigation, but the producer is, the cash deposit rate will be the 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 11.80 percent, the all-others rate established in the LTFV investigation.[23] These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) 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 the 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: July 25, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Currency Conversion
VI. Recommendation

[12] *See* 19 CFR 351.309(c).

[13] *See* 19 CFR 351.309(d).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

[15] *See* 19 CFR 351.303.

[16] *See* 19 CFR 351.310(c).

[17] *See* 19 CFR 351.310(d).

[18] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[19] *See* section 751(a)(3)(A) of the Act.

[20] *See* 19 CFR 351.212(b)(1).

[21] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[22] *See* section 751(a)(2)(C) of the Act.

[23] *See Order,* 80 FR at 39996.

Appendix II

Review-Specific Rate Applicable to Company Not Selected for Individual Review

1. Agl Co., Ltd.
2. Americana Express (Shandong) Co. Ltd.
3. Ansing Fasteners Co. Ltd.
4. Beijing Catic Industry Limited
5. Beijing Jinheung Co., Ltd.
6. Big Mind Group Co., Ltd.
7. Changzhou Kya Trading Co., Ltd.
8. China Staple Enterprise Tianjin Co. Ltd.
9. D&F Material Products Ltd.
10. De Well Group Korea Co., Ltd.
11. Dezhou Hualude Hardware Products Co. Ltd.
12. DLF Industry Co., Limited
13. Doublemoon Hardware Company Ltd.
14. DT China (Shanghai) Ltd.
15. Duo-Fast Korea Co. Ltd.
16. Ejen Brothers Limited
17. England Rich Group (China) Ltd.
18. Ever Leading International Inc.
19. Fastgrow International Co., Inc.
20. Glovis America, Inc.
21. GWP Industries (Tianjin) Co., Ltd.
22. Haas Automation Inc.
23. Han Express Co. Ltd.
24. Handuk Industrial Co., Ltd.
25. Hanmi Staple Co., Ltd.
26. Hebei Minmetals Co., Ltd.
27. Hebei Longshengyuan Trade Co Ltd.
28. Hebei Cangzhou New Century Foreign Trade Co., Ltd.
29. Hebei Shinyee Trade Co., Ltd.
30. Hengtuo Metal Products Company Limited
31. Home Value Co., Ltd.
32. Hongyi (Hk) Hardware Products Co., Limited
33. Hongyi (Hk) Industrial Co., Limited
34. Huanghua RC Business Co., Ltd.
35. Huanghua Yingjin Hardware Products Co., Ltd.
36. Inmax Industries Sdn. Bhd.
37. JCD Group Co., Limited
38. Je-il Wire Production Co., Ltd.
39. Jinheung Steel Corporation
40. Jining Jufu International Trade Co.
41. Jinsco International Corporation
42. Joo Sung Sea & Air Co., Ltd.
43. Jushiqiangsen (Tianjin) International Trade Co., Ltd.
44. Kabool Fasteners Co. Ltd.
45. KB Steel
46. Kerry-Apex (Thailand) Co., Ltd.
47. Koram Inc.
48. KPF Co., Ltd.
49. Kuehne & Nagel Ltd.
50. Linyi Double-Moon Hardware Products Co., Ltd.
51. Linyi Flyingarrow Imp. & Exp. Co., Ltd.
52. Linyi Jianchengde Metal Hardware Co.
53. Linyi Yitong Chain Co., Ltd.
54. Manho Rope and Wire Ltd.
55. Max Co., Ltd.
56. Mingguang Ruifeng Hardware Products Co., Ltd.
57. Nanjing Senqiao Trading Co., Ltd.
58. Needslink, Inc.
59. Ocean King International Industries Limited
60. Paslode Fasteners (Shanghai) Co., Ltd.
61. Peace Korea Co., Ltd.
62. Qingdao Ant Hardware Manufacturing Co., Ltd.
63. Qingdao Best World Industry-Trading Co., Ltd.
64. Qingdao Cheshire Trading Co., Ltd.
65. Qingdao Hongyuan Nail Industry Co., Ltd.
66. Qingdao Jcd Machinery Co., Ltd.
67. Qingdao Jiawei Industry Co., Limited
68. Qingdao Jisco Co., Ltd.
69. Qingdao Master Metal Products Co., Ltd.
70. Qingdao Meijialucky Industry and Co.
71. Qingdao Mst Industry And Commerce Co., Ltd.
72. Qingdao Ruitai Trade Co., Ltd.
73. Qingdao Shantron Int'l Trade Co., Ltd.
74. Qingdao Shenghengtong Metal Products Co., Ltd.
75. Qingdao Sunrise Metal Products Co., Ltd.
76. Qingdao Tian Heng Xiang Metal Products Co., Ltd.
77. Qingdao Top Metal Industrial Co., Ltd.
78. Rewon Systems, Inc.
79. Rise Time Industrial Ltd.
80. Shandong Dominant Source Group Co., Ltd.
81. Shandong Guomei Industry Co., Ltd.
82. Shanghai Curvet Hardware Products Co., Ltd.
83. Shanghai Goldenbridge International Co., Ltd.
84. Shanghai Pinnacle International Trading Co., Ltd.
85. Shanghai Zoonlion Industrial Co., Ltd.
86. Shanxi Pioneer Hardware Industrial Co., Ltd.
87. Shanxi Sanhesheng Trade Co., Ltd.
88. Shaoxing Bohui Import & Export Co., Ltd.
89. Shijiazhuang Yajiada Metal Products Co., Ltd.
90. Shijiazhuang Tops Hardware Manufacturing Co., Ltd.
91. Shin Jung TMS Corporation Ltd.
92. SSS Hardware International Trading Co., Ltd.
93. Storeit Services LLP
94. Test Rite International Co., Ltd.
95. Tangshan Jason Metal Materials Co., Ltd.
96. The Inno Steel Industry Company
97. Tianjin Bluekin Industries Limited.
98. Tianjin Coways Metal Products Co., Ltd.
99. Tianjin Hweschun Fasteners Manufacturing Co. Ltd.
100. Tianjin Jinchi Metal Products Co., Ltd.
101. Tianjin Jinghai County Hongli Industry and Business Co., Ltd.
102. Tianjin Jinzhuang New Material Sci Co., Ltd.
103. Tianjin Lianda Group Co., Ltd.
104. Tianjin Zhonglian Metals Ware Co., Ltd.
105. Tianjin Zhonglian Times Technology Co., Ltd.
106. Un Global Company Limited
107. Unicorn (Tianjin) Fasteners Co., Ltd.
108. United Company For Metal Products
109. W&K Corporation Limited
110. Weifang Wenhe Pneumatic Tools Co., Ltd.
111. Wulian Zhanpengmetals Co., Ltd.
112. WWL India Private Ltd.
113. Xian Metals And Minerals Import And Export Co., Ltd.
114. Youngwoo Fasteners Co., Ltd.
115. Zhangjiagang Lianfeng Metals Products Co., Ltd.
116. Zhaoqing Harvest Nails Co., Ltd.

[FR Doc. 2023–16199 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–428–849]

Common Alloy Aluminum Sheet From Germany: Notice of Initiation of Changed Circumstances Review, and Consideration of Revocation, in Part, of the Antidumping Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on a request from Eastman Kodak Company (Kodak), the U.S. Department of Commerce (Commerce) is initiating a changed circumstances review to consider the possible revocation, in part, of the antidumping duty (AD) order on common alloy aluminum sheet (CAAS) from Germany with respect to certain lithographic-grade aluminum sheet.

DATES: Applicable July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5193.

SUPPLEMENTARY INFORMATION:

Background

On April 27, 2021, Commerce published AD orders on CAAS from multiple countries, including Germany.[1] On May 9, 2023, Kodak, a U.S. importer of subject merchandise, requested that Commerce conduct a changed circumstances review (CCR) and revoke, in part, the *CAAS AD Order* on Germany with respect to certain lithographic-grade aluminum sheet pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(b).[2] On June 7, 2023, Commerce notified Kodak that its request for a CCR lacked certain information that was required in order for Commerce to consider the request.[3] On June 9, 2023, Kodak amended its

---

[1] *See Common Alloy Aluminum Sheet from Bahrain, Brazil, Croatia, Egypt, Germany, India, Indonesia, Italy, Oman, Romania, Serbia, Slovenia, South Africa, Spain, Taiwan, and the Republic of Turkey: Antidumping Duty Orders,* 86 FR 22139 (April 27, 2021) (*CAAS AD Order*).

[2] *See* Kodak's Letter, ''Request for Expedited Changed Circumstances Review'' dated May 9, 2023 (Request for CCR).

[3] *See* Commerce's Letter, ''Request for Additional Information'' dated June 7, 2023.

request for a CCR by providing the information that Commerce requested.[4] Specifically, Kodak provided a letter from the Aluminum Association Common Alloy Aluminum Sheet Trade Enforcement Working Group and its individual members[5] (domestic producers) in which they stated that they ''do not oppose revocation of the antidumping order on CAAS from Germany with respect to the lithographic sheet for which Kodak is seeking a partial revocation in its request for a {changed circumstances review}.''[6]

Scope of the *CAAS AD Order*

The products covered by this order is common alloy aluminum sheet, which is a flat-rolled aluminum product having a thickness of 6.3 mm or less, but greater than 0.2 mm, in coils or cut-to-length, regardless of width. Common alloy sheet within the scope of this order includes both not clad aluminum sheet, as well as multi-alloy, clad aluminum sheet. With respect to not clad aluminum sheet, common alloy sheet is manufactured from a 1XXX-, 3XXX-, or 5XXX-series alloy as designated by the Aluminum Association. With respect to multi-alloy, clad aluminum sheet, common alloy sheet is produced from a 3XXX-series core, to which cladding layers are applied to either one or both sides of the core. The use of a proprietary alloy or non-proprietary alloy that is not specifically registered by the Aluminum Association as a discrete 1XXX-, 3XXX-, or 5XXX-series alloy, but that otherwise has a chemistry that is consistent with these designations, does not remove an otherwise in-scope product from the scope.

Common alloy sheet may be made to ASTM specification B209–14 but can also be made to other specifications. Regardless of specification, however, all common alloy sheet meeting the scope description is included in the scope. Subject merchandise includes common alloy sheet that has been further processed in a third country, including but not limited to annealing, tempering, painting, varnishing, trimming, cutting, punching, and/or slitting, or any other processing that would not otherwise remove the merchandise from the scope of this order if performed in the country of manufacture of the common alloy sheet.

Excluded from the scope of this order is aluminum can stock, which is suitable for use in the manufacture of aluminum beverage cans, lids of such cans, or tabs used to open such cans. Aluminum can stock is produced to gauges that range from 0.200 mm to 0.292 mm, and has an H–19, H–41, H–48, H–39, or H–391 temper. In addition, aluminum can stock has a lubricant applied to the flat surfaces of the can stock to facilitate its movement through machines used in the manufacture of beverage cans. Aluminum can stock is properly classified under Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7606.12.3045 and 7606.12.3055.

Where the nominal and actual measurements vary, a product is within the scope if application of either the nominal or actual measurement would place it within the scope based on the definitions set for the above.

Common alloy sheet is currently classifiable under HTSUS subheadings 7606.11.3060, 7606.11.6000, 7606.12.3096, 7606.12.6000, 7606.91.3095, 7606.91.6095, 7606.92.3035, and 7606.92.6095. Further, merchandise that falls within the scope of this order may also be entered into the United States under HTSUS subheadings 7606.11.3030, 7606.12.3015, 7606.12.3025, 7606.12.3035, 7606.12.3091, 7606.91.3055, 7606.91.6055, 7606.92.3025, 7606.92.6055, 7607.11.9090. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this order is dispositive.

Proposed Partial Revocation of the CAAS AD Order on Germany

Kodak proposes that the *CAAS AD Order* on Germany be revoked, in part, with respect to lithographic-grade aluminum sheet and that Commerce amend the scope to include the following language:

Also excluded from the scope is lithographic-grade aluminum sheet. To be excluded, the lithographic-grade aluminum sheet must meet the following criteria: (i) a Copper (Cu) content of no more than 0.01 percent, a Zinc (Zn) content of ≤0.05%, a Silicon (Si) content of 0.05%–0.20% and an Iron (Fe) content of 0.30%–0.50%; (ii) a thickness between 0.267 mm–0.3705 mm, (iii) a width of 500 mm–1650 mm, (iv) a maximum wave height of no more than 3.0 mm, (v) a tensile strength of 130 MPa or more (after baking), and (vi) a surface roughness less than or equal to Ra 0.26 µm.

The designation of a product as ''lithographic-grade'' indicates the acceptability of the product for use in the production of lithographic printing plates. Importers of lithographic-grade aluminum sheet are required to maintain a certification of end use that certifies the imported lithographic-grade aluminum sheet will be used only in the production of lithographic printing plates. Importers of lithographic-grade aluminum sheet are required to maintain a copy of the end-use certifications and to provide them at the request of U.S. Customs and Border Protection or the U.S. Department of Commerce.[7]

Initiation of Partial Revocation Changed Circumstances Review

Pursuant to section 751(b) of the Act, Commerce will conduct a CCR upon receipt of a request from an interested party[8] that shows changed circumstances sufficient to warrant a review of an order. In accordance with 19 CFR 351.216(d), Commerce determines that the information submitted by Kodak, and the domestic producers'[9] statement of no opposition to the partial revocation of the *CAAS AD Order* on Germany with respect to the product described by Kodak, which is the changed circumstance under consideration, constitute a sufficient basis to conduct a changed circumstances review of the *CAAS AD Order* on Germany.

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that Commerce may revoke an order (in whole or in part) if it determines that producers accounting for substantially all the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. Commerce has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[10] In addition, in the event that Commerce determines that expedited action is

[4] *See* Kodak's Letter, ''Supplemental Questionnaire Response'' dated June 9, 2023 (Kodak's Supplemental Questionnaire Response).

[5] The individual members of the Aluminum Association Common Alloy Aluminum Sheet Trade Enforcement Working Group are: Arconic Corporation; Commonwealth Rolled Products, Inc.; Constellium Rolled Products Ravenswood, LLC; JW Aluminum Company; Novelis Corporation; and Texarkana Aluminum, Inc. *See* Kodak's Supplemental Questionnaire Response at Exhibit 1 at 2 and footnote 1.

[6] *See* Kodak's Supplemental Questionnaire Response at Exhibit 1 at 2.

[7] *See* Request for CCR at 3.

[8] Kodak reported in its May 9, 2023, request for a changed circumstances review that it is an importer of the lithographic-grade aluminum sheet that is the subject of its request. As such, Kodak is an interested party pursuant to 19 CFR 351.102(b)(29).

[9] The domestic producers qualify as interested parties under section 771 9(C) of the Act and 19 CFR 351.102(29)(v).

[10] *See, e.g., Certain Cased Pencils from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent To Revoke Order in Part,* 77 FR 42276 (July 18, 2012), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination To Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

warranted, 19 CFR 351.221(c)(3)(ii) permits Commerce to combine the notices of initiation and preliminary results of a changed circumstances review.

The domestic producers stated that they ''do not oppose revocation of the {*CAAS AD Order*} on Germany with respect to the lithographic-grade aluminum sheet for which Kodak is seeking a partial revocation in its request for a {CCR}.'' [11] However, there is no contemporaneous information on the record demonstrating that the domestic producers who are not opposed to Kodak's request currently account for substantially all the U.S. production of the domestic like product covered by the *CAAS AD Order* on Germany. Therefore, we are not combining this notice of initiation with the preliminary results of the changed circumstances review, pursuant to 19 CFR 351.221(c)(3)(ii).

Additionally, Commerce has concerns about implementing end-use certificates in connection with the requested partial revocation, as suggested by Kodak.[12] For this reason, we placed on the record a memorandum to the file in which we provide proposed revisions to Kodak's exclusion language to remove references to end-use certificates.[13] We will consider the appropriate exclusion language, as well as interested parties' comments on Commerce's proposed exclusion language, before issuing the preliminary results of this CCR.

Public Comment

Interested parties are invited to provide comments and factual information regarding this CCR, including comments on domestic industry support for the partial revocation, Commerce's proposed exclusion language, and the use of end-use certificates. Comments and factual information may be submitted to Commerce no later than 30 days after the date of publication of this notice in the **Federal Register**. Rebuttal comments and rebuttal factual information may be filed with Commerce no later than seven days after the comments and factual information are filed.[14]

All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[15] An electronically filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time on the due dates set forth in this notice. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information until further notice.[16]

Preliminary Results of the Review

Commerce intends to publish notice of the preliminary results of this CCR in the **Federal Register** in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice.

Final Results of the Review

Unless extended, Commerce will issue the final results of this changed circumstances review in accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act and 19 CFR 351.221(b)(1).

Dated: July 24, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–16093 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See* Kodak's Supplemental Questionnaire Response at Exhibit 1 at 2.

[12] *See* Request for CCR at 3.

[13] *See* Memorandum, ''Proposed Exclusion Language,'' dated concurrently with this notice (Exclusion Language Memorandum).

[14] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2).

[15] *See, generally,* 19 CFR 351.303.

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–979, C–570–980]

Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, From the People's Republic of China: Notice of Initiation of Changed Circumstances Reviews, and Consideration of Revocation of the Antidumping and Countervailing Duty Orders, in Part

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: Based on a request from SOURCE Global, PBC (SOURCE Global), the U.S. Department of Commerce (Commerce) is initiating changed circumstances reviews (CCR) to consider the possible revocation, in part, of the antidumping duty (AD) and countervailing duty (CVD) orders on crystalline silicon photovoltaic cells, whether or not assembled into modules (solar cells), from the People's Republic of China (China) with respect to certain off-grid small portable crystalline silicon photovoltaic (CSPV) panels as described below.

DATES: Applicable July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Jose Rivera, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0842.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, Commerce published the AD and CVD orders on solar cells from China.[1] On June 13, 2023, SOURCE Global, a Chinese producer and exporter of subject merchandise, requested, through CCRs, revocation of the *Orders,* in part, with respect to CSPV panels, pursuant to section 751(b)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.216(b).[2] Within SOURCE Global's CCR request, SOURCE Global included a letter from the American Alliance for Solar Manufacturing (the Alliance), a U.S. producer of the domestic like product and a petitioner in the underlying investigations, in which the Alliance stated that it did not oppose the partial revocation of the *Orders* proposed by SOURCE Global.[3] No interested parties filed comments opposing the CCR request.

Scope of the Orders

The merchandise covered by these *Orders* is crystalline silicon photovoltaic cells, and modules, laminates, and panels, consisting of crystalline silicon photovoltaic cells, whether or not partially or fully assembled into other products, including, but not limited to, modules, laminates, panels and building integrated materials.

These *Orders* cover crystalline silicon photovoltaic cells of thickness equal to or greater than 20 micrometers, having

[1] *See Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value, and Antidumping Duty Order,* 77 FR 73018 (December 7, 2012); *see also Crystalline Silicon Photovoltaic Cells, Whether or Not Assembled Into Modules, from the People's Republic of China: Countervailing Duty Order,* 77 FR 73017 (December 7, 2012) (collectively, *Orders*).

[2] *See* SOURCE Global's Letter, ''Request for Changed Circumstances Review on Certain Off-Grid Small Portable Panels,'' dated June 13, 2023 (CCR Request).

[3] *Id.* at Exhibit 15.

a p/n junction formed by any means, whether or not the cell has undergone other processing, including, but not limited to, cleaning, etching, coating, and/or addition of materials (including, but not limited to, metallization and conductor patterns) to collect and forward the electricity that is generated by the cell.

Merchandise under consideration may be described at the time of importation as parts for final finished products that are assembled after importation, including, but not limited to, modules, laminates, panels, building-integrated modules, building-integrated panels, or other finished goods kits. Such parts that otherwise meet the definition of merchandise under consideration are included in the scope of the *Orders.*

Excluded from the scope of the *Orders* are thin film photovoltaic products produced from amorphous silicon (a-Si), cadmium telluride (CdTe), or copper indium gallium selenide (CIGS).

Also excluded from the scope of the *Orders* are crystalline silicon photovoltaic cells, not exceeding 10,000mm² in surface area, that are permanently integrated into a consumer good whose function is other than power generation and that consumes the electricity generated by the integrated crystalline silicon photovoltaic cell. Where more than one cell is permanently integrated into a consumer good, the surface area for purposes of this exclusion shall be the total combined surface area of all cells that are integrated into the consumer good.

Additionally, excluded from the scope of the *Orders* are panels with surface area from 3,450 mm² to 33,782 mm² with one black wire and one red wire (each of type 22 AWG or 24 AWG not more than 206 mm in length when measured from panel extrusion), and not exceeding 2.9 volts, 1.1 amps, and 3.19 watts. For the purposes of this exclusion, no panel shall contain an internal battery or external computer peripheral ports.

Also excluded from the scope of the *Orders* are:

1. Off grid CSPV panels in rigid form with a glass cover, with the following characteristics:

(A) a total power output of 100 watts or less per panel;

(B) a maximum surface area of 8,000 cm² per panel;

(C) do not include a built-in inverter;

(D) must include a permanently connected wire that terminates in either an 8mm male barrel connector, or a two-port rectangular connector with two pins in square housings of different colors;

(E) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and

(F) must be in individual retail packaging (for purposes of this provision, retail packaging typically includes graphics, the product name, its description and/or features, and foam for transport); and

2. Off grid CSPV panels without a glass cover, with the following characteristics:

(A) a total power output of 100 watts or less per panel;

(B) a maximum surface area of 8,000 cm² per panel;

(C) do not include a built-in inverter;

(D) must include visible parallel grid collector metallic wire lines every 1–4 millimeters across each solar cell; and

(E) each panel is

1. permanently integrated into a consumer good;

2. encased in a laminated material without stitching, or

3. has all of the following characteristics: (i) the panel is encased in sewn fabric with visible stitching, (ii) includes a mesh zippered storage pocket, and (iii) includes a permanently attached wire that terminates in a female USB–A connector.

In addition, the following CSPV panels are excluded from the scope of the *Orders:* Off-grid CSPV panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water:

(A) A total power output of no more than 80 watts per panel;

(B) A surface area of less than 5,000 cm² per panel;

(C) Do not include a built-in inverter;

(D) Do not have a frame around the edges of the panel;

(E) Include a clear glass back panel; and

(F) Must include a permanently connected wire that terminates in a two-port rectangular connector.

Modules, laminates, and panels produced in a third country from cells produced in China are covered by the *Orders;* however, modules, laminates, and panels produced in China from cells produced in a third country are not covered by the *Orders.*

Additionally excluded from the scope of these *Orders* are off-grid small portable crystalline silicon photovoltaic panels, with or without a glass cover, with the following characteristics: (1) a total power output of 200 watts or less per panel; (2) a maximum surface area of 16,000 cm² per panel; (3) no built-in inverter; (4) an integrated handle or a handle attached to the package for ease of carry; (5) one or more integrated kickstands for easy installation or angle adjustment; and (6) a wire of not less than 3 meters either permanently connected or attached to the package that terminates in an 8mm diameter male barrel connector.

Merchandise covered by the *Orders* is currently classified in the Harmonized Tariff System of the United States (HTSUS) under subheadings 8501.61.0000, 8507.20.80, 8541.40.6020, 8541.40.6030, and 8501.31.8000. These HTSUS subheadings are provided for convenience and customs purposes; the written description of the scope of the *Orders* is dispositive.[4]

Proposed Partial Revocation of the Orders

The products subject to the proposed revocation are off-grid crystalline silicon photovoltaic panels in rigid form with a glass cover, with each of the following physical characteristics, whether or not assembled into a fully completed off-grid hydropanel whose function is conversion of water vapor into liquid water:

(A) A total power output of no more than 180 watts per panel at 155 degrees Celsius;

(B) A surface area of less than 16,000 square centimeters (cm²) per panel;

(C) Include a keep-out area of approximately 1,200 cm² around the edges of the panel that does not contain solar cells;

(D) Do not include a built-in inverter;

(E) Do not have a frame around the edges of the panel;

(F) Include a clear glass back panel;

(G) Must include a permanently connected wire that terminates in a two-port rounded rectangular, sealed connector;

(H) Include a thermistor installed into the permanently connected wire before the two-port connector; and

(I) Include exposed positive and negative terminals at opposite ends of the panel, not enclosed in a junction box.

Initiation of CCRs and Consideration of Revocation of the Orders, in Part

Pursuant to section 751(b)(1) of the Act, when Commerce receives information concerning, or a request from an interested party[5] for a review of, a final affirmative determination that resulted in an AD or CVD order, which

[4] *See Orders.*

[5] SOURCE Global stated in its CCR Request that it is an U.S. importer of solar panels. As such, SOURCE Global is an interested party pursuant to section 771(9)(A) of the Act and 19 CFR 351.102(b)(29)(i).

shows changed circumstances sufficient to warrant a review of an order, Commerce shall conduct a changed circumstances review of the order.[6] In accordance with 19 CFR 351.216(d), Commerce determines that the information submitted by SOURCE Global and the letter of no opposition to partial revocation of the *Orders* with respect to the products described by SOURCE Global constitute a sufficient basis to conduct CCRs of the *Orders.*[7]

Section 782(h)(2) of the Act and 19 CFR 351.222(g)(1)(i) provide that Commerce may revoke an order (in whole or in part) if it determines that producers accounting for substantially all of the production of the domestic like product have expressed a lack of interest in the order, in whole or in part. In its administrative practice, Commerce has interpreted ''substantially all'' to mean producers accounting for at least 85 percent of the total U.S. production of the domestic like product covered by the order.[8] One domestic producer, the Alliance, stated that it does not object to the partial revocation of the *Orders* proposed by SOURCE Global.

However, because the Alliance did not indicate whether it accounts for substantially all of the U.S. production of the domestic like product covered by the *Orders,* we are not combining this notice of initiation with a preliminary determination, pursuant to 19 CFR 351.221(c)(3)(ii).[9] Rather, we will provide interested parties with an opportunity to address the issue of domestic industry support with respect to the partial revocation of the *Orders,* as explained below. After examining comments, if any, concerning domestic industry support, we will issue the preliminary results of these CCRs.

Public Comment

Interested parties are invited to provide comments and/or factual information regarding these CCRs, including comments on industry support and the proposed partial revocation language. Comments and factual information may be submitted to Commerce no later than 14 days after the date of publication of this notice. Rebuttal comments and rebuttal factual information may be filed with Commerce no later than seven days after the comments and/or factual information are filed.[10] All submissions must be filed electronically using Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS).[11] An electronically filed document must be received successfully in its entirety by ACCESS, by 5 p.m. Eastern Time on the due dates set forth in this notice. Note that Commerce has temporarily modified certain requirements for serving documents containing business proprietary information, until further notice.[12]

Preliminary and Final Results of the CCRs

Commerce intends to publish in the **Federal Register** a notice of the preliminary results of these CCRs in accordance with 19 CFR 351.221(b)(4) and (c)(3)(i). Commerce will set forth its preliminary factual and legal conclusions in that notice. Pursuant to 19 CFR 351.221(b)(4)(ii), interested parties will have an opportunity to comment on the preliminary results. Unless extended, Commerce will issue the final results of these CCRs in accordance with the time limits set forth in 19 CFR 351.216(e).

Notification to Interested Parties

This initiation notice is published in accordance with section 751(b)(1) of the Act, 19 CFR 351.216(b) and 19 CFR 351.222.

Dated: July 25, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–16202 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See* 19 CFR 351.216(d).

[7] *See* CCR Request at Exhibit 15.

[8] *See, e.g., Certain Cased Pencils from the People's Republic of China: Initiation and Preliminary Results of Antidumping Duty Changed Circumstances Review, and Intent To Revoke Order in Part,* 77 FR 42276 (July 18, 2012), unchanged in *Certain Cased Pencils from the People's Republic of China: Final Results of Antidumping Duty Changed Circumstances Review, and Determination To Revoke Order, in Part,* 77 FR 53176 (August 31, 2012).

[9] In the event that Commerce determines an expedited action is warranted, 19 CFR 351.221(c)(3)(ii) permits Commerce to combine the notices of initiation and preliminary results.

[10] Submissions of rebuttal factual information must comply with 19 CFR 351.301(b)(2).

[11] *See, generally,* 19 CFR 351.303.

[12] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

National Construction Safety Team Advisory Committee Meeting

AGENCY: National Institute of Standards and Technology, Department of Commerce.

ACTION: Notice of open meeting.

SUMMARY: The National Construction Safety Team (NCST) Advisory Committee (Committee) will hold an open meeting in-person and via web conference on Thursday, September 7, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Time. The primary purposes of this meeting are to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, and progress of the NCST investigation focused on the Champlain Towers South partial building collapse that occurred in Surfside, Florida. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

DATES: The NCST Advisory Committee will meet on Thursday, September 7, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Time. The meeting will be open to the public.

ADDRESSES: The meeting will be held in person in Lecture Room D of the Administration Building, NIST, 100 Bureau Drive, Gaithersburg, Maryland 20899 and via web conference. For instructions on how to attend and/or participate in the meeting, please see the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Tanya Brown-Giammanco, Disaster and Failure Studies Program, Engineering Laboratory, NIST. Tanya Brown-Giammanco's email address is *Tanya.Brown-Giammanco@nist.gov* and her phone number is (301) 975–2822.

SUPPLEMENTARY INFORMATION: The Committee was established pursuant to section 11 of the NCST Act (Pub. L. 107–231, codified at 15 U.S.C. 7301 *et seq.*). The Committee is currently composed of eight members, appointed by the Director of NIST, who were selected on the basis of established records of distinguished service in their professional community and their knowledge of issues affecting the National Construction Safety Teams. The Committee advises the Director of NIST on carrying out the NCST Act; reviews the procedures developed for conducting investigations; and reviews the reports issued documenting investigations. Background information on the NCST Act and information on the NCST Advisory Committee is available at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee.*

Pursuant to the Federal Advisory Committee Act, as amended, 5 U.S.C. 1001 *et seq.,* notice is hereby given that the NCST Advisory Committee will

meet on Thursday, September 7, 2023, from 9:00 a.m. to 5:00 p.m. Eastern Time. The meeting will be open to the public and will be held in-person and via web conference. Interested members of the public will be able to participate in the meeting from remote locations. The primary purposes of this meeting are to update the Committee on the progress of the NCST investigation focused on the impacts of Hurricane Maria in Puerto Rico, and progress of the NCST investigation focused on the Champlain Towers South partial building collapse that occurred in Surfside, Florida. The agenda may change to accommodate Committee business. The final agenda will be posted on the NIST website at *https://www.nist.gov/topics/disaster-failure-studies/national-construction-safety-team-ncst/advisory-committee-meetings.*

Individuals and representatives of organizations who would like to offer comments and suggestions related to items on the Committee's agenda for this meeting are invited to request a place on the agenda. Approximately twenty minutes will be reserved for public comments and speaking times will be assigned on a first-come, first-served basis. The amount of time per speaker will be determined by the number of requests received. This meeting will be recorded. Questions from the public will not be considered during this period. All those wishing to speak must submit their request by email to the attention of Taylor Morgan at *taylor.morgan@nist.gov* by 5:00 p.m. Eastern Time, Monday, August 28, 2023. Any member of the public is also permitted to file a written statement with the advisory committee; speakers who wish to expand upon their oral statements, those who wish to speak but cannot be accommodated on the agenda, and those who are unable to attend are invited to submit written statements electronically by email to *disaster@nist.gov.*

All visitors to the NIST site are required to pre-register to be admitted. Anyone wishing to attend this meeting in-person or via web conference must register by 5:00 p.m. Eastern Time, Monday, August 28, 2023, to attend. Please submit your full name, the organization you represent (if applicable), email address, and phone number to Taylor Morgan at *taylor.morgan@nist.gov.* Non-U.S. citizens must submit additional information; please contact Taylor Morgan at *taylor.morgan@nist.gov.* For participants attending in person, please note that federal agencies, including NIST, can only accept a state issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. For detailed information please contact Taylor Morgan or visit: *http://www.nist.gov/public_affairs/visitor/.*

Alicia Chambers,

NIST Executive Secretariat.

[FR Doc. 2023–16126 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD161]

Gulf of Mexico Fishery Management Council; Public Hearings

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

ACTION: Notice; public hearings and webinars.

SUMMARY: The Gulf of Mexico Fishery Management Council (Council) will hold three virtual/webinar public hearings to solicit public comments on Joint Amendment with the Gulf and South Atlantic Council's to Address Electronic Reporting for Commercial Vessels participating in the coastal logbook program.

DATES: The public hearings will take place August 23, 2023 at 12 p.m., EDT, August 29, 2023 at 6 p.m., EDT and August 30, 2023 at 10 a.m., EDT and will conclude no later than 3 hours after the start time of each webinar. For specific dates and times, see **SUPPLEMENTARY INFORMATION**. Written public comments must be received on or before 5 p.m. EDT on October 17, 2023.

ADDRESSES: Please visit the Gulf Council website at *www.gulfcouncil.org* for meeting materials and webinar registration information. If you prefer to ''listen in'', you may access the log-on information by visiting our website at *www.gulfcouncil.org.*

Meeting addresses: The public hearings will be held via virtual/webinars. For specific locations, see **SUPPLEMENTARY INFORMATION**.

Public comments: Comments may be submitted online through the Council's public portal by visiting *www.gulfcouncil.org* and clicking on ''CONTACT US''.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein; Public Information Officer; email: *emily.muehlstein@gulfcouncil.org,* Gulf of Mexico Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The agenda for the following three webinar public hearings are as follows: Council and NOAA staff will begin with a presentation on the proposed management change addressed in the Amendment Addressing Electronic Reporting for Commercial Vessels. The Gulf and South Atlantic Councils are currently considering requiring federal commercial permit holders to submit commercial coastal logbooks electronically, rather than mailing paper logbooks. This amendment would impact commercial Reef Fish and Coastal Migratory Pelagic permit holders in the Gulf of Mexico and commercial Snapper/Grouper and Dolphin/Wahoo permit holders in the South Atlantic.

Staff and a Council member will be available to answer any questions, and the public will have the opportunity to provide testimony on the amendment and other related testimony at the end of each public hearing webinar.

Webinars

Monday, August 23, 2023; webinar to begin at 12 p.m., EDT.

Tuesday, August 29, 2023; webinar to begin at 6 p.m., EDT.

Wednesday, August 30, 2023; webinar to begin at 10 a.m., EDT.

Visit *www.gulfcouncil.org* website and click on the ''meetings'' tab for registration information. After registering, you will receive a confirmation email containing information about joining the webinar.

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

Dated: July 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–16204 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD200]

New England Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public hybrid meeting of its Risk Policy Working Group (RPWG) to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). This meeting will be held in-person with a webinar option. Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This meeting will be held on Tuesday, August 22, 2023, at 9 a.m.

ADDRESSES: This meeting will be held at the Four Points by Sheraton, One Audubon Road, Wakefield, MA 01880; telephone: (781) 245–9300.

Webinar registration URL information: https://attendee.gotowebinar.com/register/7355629868155270240.

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The RPWG will address the terms of reference (TORs) approved by the Council, including progress made in reviewing the Council's current Risk Policy, and Risk Policy Road Map (TOR 1). The RPWG will also begin considering possible changes to the Risk Policy (TOR 2), focusing on goals and objectives, identifying and defining key terms, and outlining how an updated Risk Policy could interact with existing ABC control rules used in each of the Council's Fishery Management Plans. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: July 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–16203 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD184]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish Research Set-Aside (RSA) Working Group via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Monday, August 21, 2023, at 1 p.m.

ADDRESSES: Webinar registration URL information: *https://attendee.gotowebinar.com/register/2903308747268903 31.*

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Monkfish Research Set-Aside Working Group will meet to identify final recommendations on any preferred improvements to the RSA program and provide any final input on the report. The recommendations and the report will be provided to the Monkfish Plan Development Team, Advisory Panel, and Committee for their consideration when they make initial recommendations for 2024 NEFMC work priorities. These recommendations will be considered at the September 2023 NEFMC meeting. Other business may be discussed, as necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Thomas A. Nies, Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: July 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–16207 Filed 7–28–23; 8:45 am]

BILLING CODE 3510–22–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Instructions for AmeriCorps State and National Competitive, New, and Continuation Grants

AGENCY: Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: The Corporation for National and Community Service, operating as AmeriCorps, has submitted a public information collection request (ICR) entitled Application Instructions for AmeriCorps State and National Competitive, New, and Continuation Grants for review and approval in

accordance with the Paperwork Reduction Act.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by August 30, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Copies of this ICR, with applicable supporting documentation, may be obtained by calling AmeriCorps, Arminda Pappas, at (202) 606–6659 or by email to *apappas@cns.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on April 26, 2023 at 88 FR 25384. This comment period ended June 26, 2023. No public comments were received from this Notice.

Title of Collection: Application Instructions for AmeriCorps State and National Competitive New and Continuation Grants.

OMB Control Number: 3045–0047.

Type of Review: Renewal.

Respondents/Affected Public: Businesses and Organizations.

Total Estimated Number of Annual Responses: 450.

Total Estimated Number of Annual Burden Hours: 18,000.

Abstract: The application instructions conform to AmeriCorps' online grant application system, eGrants, which applicants must use to respond to AmeriCorps Notices of Funding Opportunities. AmeriCorps seeks to renew the current information collection with revisions. The revisions are intended to update sections of the Application Instructions that have been amended. The information collection will otherwise be used in the same manner as the existing application. AmeriCorps also seeks to continue using the current application until the revised application is approved by OMB. The current application is due to expire on September 30, 2023.

Sonali Nijhawan,

Director, AmeriCorps State and National.

[FR Doc. 2023–16168 Filed 7–28–23; 8:45 am]

BILLING CODE 6050–28–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application Package for AmeriCorps Application Questions

AGENCY: The Corporation for National and Community Service.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, the Corporation for National and Community Service (operating as AmeriCorps) is proposing to renew an information collection.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by September 29, 2023.

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 Sharron Tendai, 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: Sharron Tendai, 202–606–3904, or by email at *stendai@cns.gov*.

SUPPLEMENTARY INFORMATION:

Title of Collection: AmeriCorps Application Questions.

OMB Control Number: 3045–0187.

Type of Review: Renewal.

Respondents/Affected Public: Organizations, State, Local or Tribal Governments.

Total Estimated Number of Annual Responses: 13,200.

Total Estimated Number of Annual Burden Hours: 79,200.

Abstract: The generic application questions are used by applicants for funding through AmeriCorps competitions. The application is completed electronically using the Agency's web-based grants management system or submitted via email. AmeriCorps also seeks to continue using the currently approved information collection until the revised information collection is approved by OMB. The currently approved information collection is due to expire on October 30, 2023.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information. Burden means the total time, effort, or financial resources expended by persons to

generate, maintain, retain, disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information; and to transmit or otherwise disclose the information. All written comments will be available for public inspection on *regulations.gov*.

Danielle Melfi,

Chief Program Officer.

[FR Doc. 2023–16085 Filed 7–28–23; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Business Board; Notice of Federal Advisory Committee Meeting

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

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Business Board (''the Board'') will take place.

DATES: Closed to the public Wednesday, August 2, 2023 and Thursday, August 3, 2023.

ADDRESSES: The closed meeting will be in rooms 1E840 and 4D880 in the Pentagon, and at The White House, Washington DC.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Hill, Designated Federal Officer (DFO) of the Board in writing at Defense Business Board, 1155 Defense Pentagon, Room 5B1088A, Washington, DC 20301–1155; or by email at *jennifer.s.hill4.civ@mail.mil;* or by phone at 571–342–0070.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Due to circumstances beyond the control of the Department of Defense and the Designated Federal Officer, the Defense Business Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its August 2–3, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

Purpose of the Meeting: The mission of the Board is to examine and advise the Secretary of Defense on overall DoD management and governance. The Board provides independent, strategic-level, private sector and academic advice and counsel on enterprise-wide business management approaches and best practices for business operations and achieving National Defense goals.

Agenda: The Board will hold a closed meeting on August 2 and August 3. The DFO will open the closed meeting followed by a welcome by Board Chair, Hon. Deborah James. The Board will receive classified discussions on Space Force Modernization and Joint Force Integration from General David D. Thompson, Vice Chief of Space Operations; Assessing Innovation Through the NDAA from Hon. Kathleen Hicks, Deputy Secretary of Defense; DoD Current Affairs from Hon. Lloyd Austin, Secretary of Defense; and Artificial Intelligence/Machine Learning Scaffolding from Mr. Joe Larson, Deputy Director of the Chief Digital and Artificial Intelligence Office for Algorithmic Warfare. After a break, the board will receive a classified update on the Globally Integrated Wargame and Recommendations from Lt Gen Dagvin R.M. Anderson (USAF), Director for Joint Force Development; a classified discussion on Joint Force Capabilities Integration from ADM Michael Gilday, Chief of Naval Operations; and the State of the National Guard from GEN Daniel R. Hokanson, Chief of the National Guard Bureau. The Board will take a short break, then receive remarks by Board Chair, Hon Deborah James and Deputy Secretary, Hon. Kathleen Hicks. Next, the board will hear a classified update on the DBB Improving IT User Experience Study from Hon. John Sherman, Department of Defense Chief Information Officer. The DFO will adjourn the closed meeting. The Board will begin in closed meeting on August 3 at The White House. The DFO will open the closed meeting followed by the Chair's welcome. Next the board will have a classified discussion on the U.S. Economic Outlook and Recent NATO Summit from Mr. Jeff Zients, White House Chief of Staff, and Mr. Jake Sullivan, National Security Advisor. The DFO will then adjourn the closed meeting.

The latest version of the agenda will be available on the Board's website at: *https://dbb.dod.afpims.mil/Meetings/Meeting-Aug-2023/*.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, it is hereby determined that the August 2–3 meeting of the Board will include classified information and other matters covered by 5 U.S.C. 552b(c)(1) and that, accordingly, the meeting will be closed to the public. This determination is based on the consideration that it is expected that discussions throughout these periods will involve classified matters of national security. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of these portions of the meeting. To permit these portions of the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the Board's findings and recommendations to the Secretary of Defense and to the Deputy Secretary of Defense.

Written Comments and Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and 5 U.S.C. 1009(a)(3) of the FACA, the public or interested organizations may submit written comments or statements to the Board in response to the stated agenda of the meeting or regarding the Board's mission in general. Written comments or statements should be submitted to Ms. Jennifer Hill, the DFO, via electronic mail (the preferred mode of submission) at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. The DFO must receive written comments or statements submitted in response to the agenda set forth in this notice by Monday, July 31, 2023, to be considered by the Board. The DFO will review all timely submitted written comments or statements with the Board Chair and ensure the comments are provided to all members of the Board before the meeting. Written comments or statements received after this date may not be provided to the Board until its next scheduled meeting. Please note that all submitted comments and statements will be treated as public documents and will be made available for public inspection, including, but not limited to, being posted on the Board's website.

Dated: July 25, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–16115 Filed 7–28–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Research and Engineering, Department of Defense (DoD).

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal Advisory Committee meeting of the Defense Science Board (DSB) will take place.

DATES: Closed to the public Wednesday, August 16, 2023 from 8:00 a.m. to 5:00 p.m.; Thursday, August 17, 2023 from 8:00 a.m. to 5:00 p.m.; and Friday, August 18, 2023 from 8:00 a.m. to 12:00 p.m.

ADDRESSES: The address of the closed meeting is the Executive Conference Center, 4075 Wilson Blvd., Floor 3, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Doxey, Designated Federal Officer (DFO), (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *kevin.a.doxey.civ@mail.mil* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act (FACA)''), 5 U.S.C. 552b(c) (commonly known as the ''Government in the Sunshine Act''), and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR).

Purpose of the Meeting: The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will meet to discuss the 2023 DSB Summer Study on Climate Change and Global Security (''the DSB Summer Study'').

Agenda: The meeting will begin on Wednesday, August 16, 2023 at 8:00 a.m. with administrative opening remarks from Mr. Kevin Doxey, DFO and Executive Director, and a classified overview of the Summer Study to date from Dr. Eric Evans, the DSB Chair. Next, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Following break, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Next, members will meet in a breakout session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 5:00 p.m. On Thursday, August 17, 2023, the DSB members will meet in a breakout session with subject matter experts from United States Africa Command to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The members will then meet in a breakout session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Next, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 5:00 p.m. On Friday, August 18, 2023, the DSB members will meet in a breakout session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 12:00 p.m.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, the DoD has determined that the DSB meeting will be closed to the public. Specifically, the Under Secretary of Defense for Research and Engineering, in consultation with the DoD Office of the General Counsel, has determined in writing that the meeting will be closed to the public because it will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meeting. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the Under Secretary of Defense for Research and Engineering.

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR 102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section at any point; however, if a written statement is not received at least three calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: July 25, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–16120 Filed 7–28–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0144]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for the Fulbright-Hays Group Projects Abroad (GPA) Program (1894–0001)

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before August 30, 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 Cory Neal, 202–987–0438.

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: Application for the Fulbright-Hays Group Projects Abroad (GPA) Program (1894–0001).

OMB Control Number: 1840–0792.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Private Sector.

Total Estimated Number of Annual Responses: 60.

Total Estimated Number of Annual Burden Hours: 6,600.

Abstract: Under the Fulbright-Hays Group Projects Abroad (GPA) program, the Secretary awards grants to eligible institutions, departments, and organizations to conduct overseas group projects in research, training, and curriculum development. These institutions administer the program in cooperation with the U.S. Department of Education (US/ED) as provided under the authority of sections 102(b)(6) and 104(e)(1) of the Mutual Educational and Cultural Exchange Act of 1961, 34 CFR part 662, the Policy Statements of the J. William Fulbright Foreign Scholarship Board (FSB), and the Education Department General Administrative Regulations (EDGAR).

This is a revision to an existing collection. ED/IFLE is removing Competitive Preference Priority 6: Thematic Focus on Ukraine or Afghanistan because only 1 applicant out of 43 applications for FY 2023 applied for the priority. This applicant was not eligible for the points. No applications received points for this priority. This revision will have no effect on hour or cost burden.

This collection is being submitted under the Streamlined Clearance Process for Discretionary Grant Information Collections (1894–0001). Therefore, the 30-day public comment period notice will be the only public comment notice published for this information collection.

Dated: July 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. 2023–16139 Filed 7–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0069]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; REL Pacific Efficacy and Implementation Evaluation of the Secondary Writing Toolkit

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before August 30, 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 Anousheh Shayestehpour, 202–987–1148.

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: REL Pacific Efficacy and Implementation Evaluation of the Secondary Writing Toolkit.

OMB Control Number: 1850–NEW.

Type of Review: A new ICR.

Respondents/Affected Public: Individuals and Households.*Total Estimated Number of Annual Responses:* 1,705.

Total Estimated Number of Annual Burden Hours: 416.

Abstract: The current authorization for the Regional Educational Laboratories (REL) program is under the Education Sciences Reform Act of 2002, part D, section 174, (20 U.S.C. 9564), administered by the Department of Education, Institute of Education Sciences (IES), National Center for Education Evaluation and Regional Assistance (NCEE). The central mission and primary function of the RELs is to support applied research and provide technical assistance to state and local education agencies within their region (ESRA, part D, section 174[f]). The REL program's goal is to partner with educators and policymakers to conduct work that is change-oriented and supports meaningful local, regional, or state decisions about education policies, programs, and practices to improve outcomes for students.

Literacy, including writing, is closely tied to student success throughout K–12 education, which impacts high school graduation (National Institute for Literacy, 2008; NCES, 2020) and ultimately, income beyond graduation (US Bureau of Labor Statistics, 2019). Despite the importance of writing to life and learning, teachers report that the training they receive on teaching writing, both prior to entering the field

and while teaching, is minimal or insufficient (Graham, 2019). To address this problem, the REL PA toolkit development team is developing a Secondary Writing Toolkit to support teachers in implementing Hawai'i evidence-based instructional strategies to improve writing among students in grades 6–8. The toolkit is based on the Teaching Secondary Students to Write Effectively WWC Practice Guide and is being developed in collaboration with district and school partners in Hawai'i.

REL Pacific will design the Toolkit to help teachers improve their writing instruction so that students in Hawai'i become stronger, more effective writers. The Toolkit uses Professional Learning Communities (PLCs) facilitated by one of the teachers in the school (peer facilitator) to help teachers learn new instructional skills. Teachers also have access to instructional resources as part of the Toolkit to support their use of evidence-based strategies in their classrooms.

This study is designed to measure the efficacy and implementation of the REL Pacific-developed toolkit designed to improve writing among students in grades 6–8. The toolkit evaluation team plans to conduct an independent evaluation using a school-level, cluster randomized controlled trial design to assess the efficacy of the school-based professional learning resources included in the toolkit. The evaluation will also assess how teachers and facilitators implement the toolkit to provide context for the efficacy findings and guidance to improve the toolkit and its future use. The evaluation will take place in 40 schools in Hawai'i and focus on all students in grades 6–8. The toolkit evaluation will produce a report for district and school leaders who are considering strategies to improve writing among secondary students. The report will provide guidance on using the Toolkit professional development and resources to help teachers implement the Practice Guide (PG) recommendations.

Dated: July 26, 2023.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–16177 Filed 7–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0077]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Program for International Student Assessment 2025 (PISA 2025) Main Study Recruitment and Field Test

AGENCY: National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before August 30, 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 Carrie Clarady, 202–245–6347.

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: Program for International Student Assessment 2025 (PISA 2025) Main Study Recruitment and Field Test.

OMB Control Number: 1850–0755.

Type of Review: A revision of a currently approved ICR.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 58,672.

Total Estimated Number of Annual Burden Hours: 18,903.

Abstract: The Program for International Student Assessments (PISA) is an international assessment of 15-year-olds, which focuses on assessing students' reading, mathematics, and science literacy. PISA was first administered in 2000 and is typically conducted every three years. The United States has participated in all of the previous cycles and planned to participate in 2021 in order to track trends and to compare the performance of U.S. students with that of students in other education systems. PISA is sponsored by the Organization for Economic Cooperation and Development (OECD). In the United States, PISA is conducted by the National Center for Education Statistics (NCES), within the U.S. Department of Education.

In each administration of PISA, one of the subject areas (reading, mathematics, or science literacy) is the major domain and has the broadest content coverage, while the other two subjects are the minor domains. PISA emphasizes functional skills that students have acquired as they near the end of mandatory schooling (aged 15 years), and students' knowledge and skills gained both in and out of school environments. Other areas may also be assessed, such as, in the case of PISA 2025, Learning in a Digital World (LDW), which will be an innovative domain in 2025. PISA assesses students' knowledge and skills gained both in and out of school environments. In addition to the cognitive assessments described above, PISA 2025 will include questionnaires administered to school principals and assessed students. To prepare for the main study, PISA countries will conduct a field test in the spring of the year previous, primarily to evaluate newly developed assessment and questionnaire items but also to test the assessment operations. This request is to conduct PISA 2025 main study recruitment and the PISA 2025 field test. This submission requests all burden for both the field test (scheduled for early 2024) and the main study (scheduled for late 2025), and presents materials (including recruitment and

communications materials) and the final international drafts of the field test instruments. As part of this submission, NCES is publishing a notice in the **Federal Register** allowing first a 60- and then a 30-day public comment period. We anticipate that some materials will be revised after the 60-day public comment period and encourage stakeholders to see individual documents for details. The materials that will be used in the 2025 main study will be based upon the field test materials included in this submission. Additionally, this submission is designed to adequately justify the need for and overall practical utility of the full study and to present the overarching plan for all of the phases of the data collection, providing as much detail about the measures to be used as is available at the time of this submission.

We plan to submit a revision (along with a 30-day public comment period) in October 2023 in order to clear the final US version of the field test instrument, as well as finalize any updated materials for use in the 2024 field test. In order to begin recruiting schools for the main study by October 2024, we will submit a change-request to OMB in May 2024 with the final main study recruitment materials and parental consent letters, details about any changes to the design and procedures for the main study, and updates to the respondent burden estimates for the main study data collection. Subsequently in spring 2025 we will submit a clearance request, with a 30-day public comment period notice published in the **Federal Register**, with the final main study procedures and instruments for data collection in the fall of 2025.

Dated: July 26, 2023.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–16179 Filed 7–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Western Area Power Administration

Agency Information Collection Extension

AGENCY: Western Area Power Administration, Department of Energy.

ACTION: Notice and request for comments.

SUMMARY: The Western Area Power Administration (WAPA), pursuant to the Paperwork Reduction Act of 1995, intends to extend an information collection request with the Office of Management and Budget (OMB) for 3 years with ministerial changes. The current OMB control number 1910–5136 for WAPA's Applicant Profile Data (APD) form expires March 31, 2024. WAPA intends to extend the APD form under the OMB control number to March 31, 2027. WAPA is seeking comments on this proposed information collection extension.

DATES: Comments regarding this proposed information collection must be received on or before the end of the comment period that closes on September 29, 2023. If you anticipate any difficulty in submitting comments within that period, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

ADDRESSES: Written comments may be sent to Mr. Christopher Magee, Records and Information Management Program Manager, Western Area Power Administration, P.O. Box 281213, Lakewood, CO 80228, or by email to *records@wapa.gov.* Please refer to ''Paperwork Reduction Act Information Collection'' as the subject of your comments.

FOR FURTHER INFORMATION CONTACT: Please contact Mr. Christopher Magee, Records and Information Management Program Manager, Western Area Power Administration, PO Box 281213, Lakewood, CO 80228, telephone 720–962–7139, or email *cmagee@wapa.gov.* The proposed APD form is available on WAPA's website at *www.wapa.gov/PowerMarketing/Pages/applicant-profile-data.aspx.*

SUPPLEMENTARY INFORMATION: Comments are invited on: (a) Whether the extended 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, 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 through the use of automated collection techniques or other forms of information technology.

This information collection request relates to: (1) *OMB No.:* 1910–5136; (2) *Information Collection Request Title:* Western Area Power Administration Applicant Profile Data; (3) *Type of Review:* Renewal; (4) *Purpose:* The proposed collection of information is necessary for the proper performance of WAPA's power marketing functions. WAPA markets a limited amount of Federal hydropower and has discretion to determine who will receive an allocation of Federal hydropower. Due to the limited quantity and high demand for WAPA's hydropower available under established marketing plans, WAPA may need to collect information using the APD to evaluate the entities applying to receive allocations of Federal hydropower; (5) *Annual Estimated Number of Respondents:* 33; (6) *Annual Estimated Number of Total Responses:* 33; (7) *Annual Estimated Number of Burden Hours:* 250; and (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $37,221.50.

I. Statutory Authority

The Reclamation Act of 1902 established the Federal reclamation program.[1] The basic principle of the Reclamation Act of 1902 was that the United States, through the Secretary of the Interior, would build and operate irrigation works from the proceeds of public land sales in sixteen arid Western states (a seventeenth, Texas, was added in 1906). The Reclamation Project Act of 1939 expanded the purposes of the reclamation program and specified certain terms for contracts that the Secretary of the Interior enters into to furnish water and power.[2] Congress enacted the Reclamation Laws for purposes that include enhancing navigation, protection from floods, reclaiming the arid lands in the Western United States, and for fish and wildlife.[3] Congress intended that the production of power would be a supplemental feature of the multi-purpose water projects authorized under the Reclamation Laws.[4] Section 9 of the Reclamation Project Act of 1939 provides that no contract entered into by the United States for power may, in the judgment of the Secretary, ''impair the efficiency of the project for irrigation purposes.'' [5] Section 5 of the Flood Control Act of 1944, as amended,[6] is read *in pari materia* with the Reclamation Laws with respect to

[1] *See* Act of June 17, 1902, ch. 1093, 32 Stat. 388 (1902), as amended and supplemented.

[2] *See* Act of Aug. 4, 1939, ch. 418, 53 Stat. 1187 (1939), as amended and supplemented.

[3] *See, e.g.,* Act of Oct. 26, 1937, ch. 832, 50 Stat. 844, 850 (1937), as amended and supplemented.

[4] *See id.*

[5] 43 U.S.C. 485h(c)(1).

[6] 16 U.S.C. 825s.

WAPA.[7] In 1977, section 302 of the Department of Energy Organization Act transferred the power marketing functions of the Department of the Interior to the Secretary of Energy, acting by and through a separate Administrator for WAPA.[8] Under this authority, WAPA markets Federal hydropower. As part of WAPA's marketing authority, WAPA needs to obtain information from interested entities who desire an allocation of Federal power using the APD form. The Paperwork Reduction Act of 1995 requires WAPA to obtain a clearance from OMB before collecting this information through the APD form.[9]

II. This Process Determines the Format of the APD and Is Not a Call for Applications

This public process and the associated **Federal Register** notice only determine the information that WAPA will collect from an entity desiring to apply for a Federal power allocation. This public process is a legal requirement that WAPA must fulfill before WAPA can request information from potential preference customers.

This public process is not the process whereby interested parties request an allocation of Federal power. The actual allocation of power is outside the scope of this proceeding. Please do not submit a request for Federal power in this process. Later, and as appropriate, WAPA will issue calls for applications as part of project-specific marketing plans. When WAPA issues a call for applications, the information WAPA proposes to collect is voluntary. WAPA will use the information collected, in conjunction with its project–specific marketing plans, to determine an entity's eligibility, and ultimately which entities will receive an allocation of Federal power.

III. Invitation for Comments

WAPA intends to extend and reuse the APD form approved under OMB control number 1910–5136. The extension would continue use of the form through March 31, 2027. WAPA is proposing some ministerial changes to the APD. The proposed APD form, including a list of ministerial changes and the reason for such changes, is available on WAPA's website at *http://www.wapa.gov/PowerMarketing/Pages/applicant-profile-data.aspx.* Comments are invited on: (1) whether the extended collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (2) the accuracy of the agency's estimate of the burden of the 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 applicants, including the use of automated electronic, mechanical or other collection techniques, or other forms of information technology. After considering all public comments, WAPA will publish a second notice in the **Federal Register** submitting the APD to OMB.

Signing Authority

This document of the Department of Energy was signed on July 24, 2023, by Tracey LeBeau, Administrator, 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**.

Treena V. Garrett,

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

[FR Doc. 2023–16163 Filed 7–28–23; 8:45 am]

BILLING CODE 6450–01–P

[7] *See, e.g., United States* v. *Sacramento Mun. Util. Dist.,* 652 F.2d 1341, 1345 n.4 (9th Cir. 1981) (citing *N. Cal. Power Agency* v. *Morton,* 396 F. Supp. 1187, 1189 (D.D.C. 1975). *See also* Disposition of Surplus Power Generated at Clark Hill Reservoir Project, 41 Op. Att'y Gen. 236, 245 (1955).

[8] *See* 42 U.S.C. 7152(a)(1)(E).

[9] *See* 44 U.S.C. 3501 *et seq.*

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2023–0314; 11242–01–OAR]

Notice of Proposed Information Collection Request; Indoor airPLUS Program

AGENCY: Office of Radiation and Indoor Air, Environmental Protection Agency (EPA).

ACTION: Notice; opening of a 60-day public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''EPA's Indoor airPLUS Program'' (EPA ICR No. 2763.01, OMB Control No. 2060–NEW) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. 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.

DATES: Comments must be submitted on or before September 29, 2023.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2023–0314 by any of the following methods:

- *Federal eRulemaking Portal https://www.regulations.gov* (our preferred method). Follow the online instructions for submitting comments.
- *Email: Indoor_airPLUS@epa.gov.* Include Docket ID No. EPA–HQ–OAR–2023–0314 in the subject line of the message.
- *U.S. Postal Service Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Air and Radiation Docket, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.
- *Hand Delivery/Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operation are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. EPA–HQ–OAR–2023–0314. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments, see the **SUPPLEMENTARY INFORMATION** section of this document.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Peggy Bagnoli, Indoor Environments Division, Office of Radiation and Indoor Air 6609T, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 343–9398; fax number:

(202) 343–2393; email address: *Indoor_airPLUS@epa.gov.*

SUPPLEMENTARY INFORMATION: 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.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Indoor airPLUS is aimed at forming public-private partnerships that help prevent various forms of indoor air pollution and their associated health risks. This ICR covers information collection activities under the EPA's newly revised Indoor airPLUS program. Indoor airPLUS is a voluntary certification labeling program that represents value-added marketability that home builders, verification companies, and oversight organizations can use to distinguish themselves from competition, while homeowners see increased comfort and a healthier and safer home with improved indoor air quality (IAQ) by requiring construction practices and product specifications that minimize exposure to airborne pollutants and contaminants.

Form Numbers:

- A Partnership Agreement for Home Builder/Verification Organization/Home Certification Organizations (Voluntary)
- Indoor airPLUS Verification Checklist/Home Certification Organizations Certification Process (Voluntary)
- Indoor airPLUS Quarterly Reporting for Homebuilders/Raters (Voluntary)
- Leader Award Applications Builder/Affordable Builder/Rater (Voluntary)

Respondents/affected entities: Respondents for this information collection request include Indoor airPLUS partners, including homebuilders and developers, verification organizations (raters and rating providers), and home certification organizations. The following is a list of Standard Industrial Classification (SIC) codes and corresponding North American Industry Classification System (NAICS) codes for industry segments which may be affected by information collections covered under this ICR for the Indoor airPLUS Program: Utilities (22), Construction (23), Retail Trade (44–45), Transportation and Warehousing (48–49), Finance and Insurance (52), Real Estate and Rental and Leasing (53), Professional, Scientific, and Technical Services (54), and Public Administration (92).

Respondent's obligation to respond: voluntary (Clean Air Act, section 103).

Estimated number of respondents: 566 new and 2,142 active participants respondents from section 6 of the ICR (total).

Frequency of response: Once per year (on average).

Total estimated burden: 11,205 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $1,136,611 (per year), includes $0 annualized capital or operation & maintenance costs.

Changes in estimates: This is a new ICR, no changes in burden currently applicable.

Jonathan D. Edwards,

Director, Office of Radiation and Indoor Air.

[FR Doc. 2023–16195 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2016–0027; FRL–11136–01–OAR]

Proposed Information Collection Request; Comment Request; Information Collection Request (ICR) for On-Highway Motorcycle Certification and Compliance Program; EPA

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), ''Information Collection Request (ICR) for On-Highway Motorcycle Certification and Compliance Program'' (EPA ICR Number 2535.03, OMB Control Number 2060–0710) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through October 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.

DATES: Comments must be submitted on or before September 29, 2023.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2016–0027, 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.

FOR FURTHER INFORMATION CONTACT: Julian Davis, Environmental Protection Agency, 2000 Traverwood, Ann Arbor, MI 48105; telephone number: (734) 214–4029; fax number: (734) 214–4869; email address: *davis.julian@epa.gov.*

SUPPLEMENTARY INFORMATION: 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.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: Under the Clean Air Act (42 U.S.C. 7521 *et seq.*) manufacturers and importers of on-highway motorcycles must have a certificate of conformity issued by EPA covering any vehicle they intend to offer for sale in the United States. A certificate of conformity represents that the respective vehicle conforms to all applicable emissions requirements. In issuing a certificate of conformity, EPA reviews vehicle information and emissions test data to determine if the required testing has been performed and the required emissions levels have been demonstrated. After a certificate of conformity has been issued, the Agency may request additional information to verify that the product continues to meet its certified emissions standards throughout its useful life.

Form Numbers:

Form title	New or previous	Current form No.
Highway Motorcycle HC+NO_X Average Exhaust Emissions Model Year Report	Previous	5900–339
Manufacturer Production Report for Engine/Equipment Manufacturers—Heavy-Duty, Nonroad, and Highway Motorcycles.	Previous	5900–90
List of Emissions Related Components	New.	
Catalyst Information	Previous	5900–464
AECD Reporting Template	New.	

Respondents/affected entities: Entities potentially affected by this action are on-highway motorcycle manufacturers and importers.

Respondent's obligation to respond: Mandatory (40 CFR part 86).

Estimated number of respondents: 95 (total).

Frequency of response: Annual, unless otherwise specified under 40 CFR part 86, subpart E.

Total estimated burden: 5,832 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $1,124,869 (per year), includes $31,998 annualized capital and $342,565 operation & maintenance costs.

Changes in estimates: There is an increase of 379 hours but a decrease of $63,760 in the total estimated cost from the previous ICR. This increase in hours but decrease in total estimated cost is primarily due to the inclusion of electric motorcycle manufacturers who must certify their engine families but are not subject to exhaust or evaporative emissions testing requirements.

Byron J. Bunker,

Director, Compliance Division, Office of Transportation and Air Quality.

[FR Doc. 2023–16193 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R02–OAR–2023–0370; FRL–11172–01–R2]

Air Pollution Control; Proposed Administrative Action on Clean Air Act Grant to the Puerto Rico Department of Natural and Environmental Resources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed administrative action to revoke a grant; request for comments; and notice of opportunity for public hearing.

SUMMARY: The EPA is proposing to revoke the Fiscal Year 2019 Clean Air Act (CAA) section 105 grant awarded to the Puerto Rico Department of Natural and Environmental Resources (PRDNER) because it has failed to satisfy the statutory maintenance of effort (MOE) requirement for that year. The EPA is providing prior notice of its intent to revoke PRDNER's Fiscal Year 2019 Clean Air Act section 105 grant. When the proposed action is final, PRDNER will be eligible to receive future CAA section 105 grants to support its air pollution control program.

DATES: Comments and/or requests for a public hearing must be received by EPA at the address stated below by August 30, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R02–OAR–2023–0370 at *https://www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Proprietary Business Information (PBI) or Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

https://www.epa.gov/dockets/commenting-epa-dockets. If you need assistance in a language other than English or if you are a person with disabilities 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: Carmen R. Guerrero Pérez, Director, Caribbean Environmental Protection Division, United States Environmental Protection Agency—Region 2, City View Plaza II—Suite 700, #48 Rd. 165 km 1.2, Guaynabo, PR 00968–8069. Telephone (787) 977–5802, Email Address: *guerrero.carmen@epa.gov.*

SUPPLEMENTARY INFORMATION: Section 105 of the Clean Air Act (CAA) provides grant funding for the continuing air programs of eligible State, local, and Tribal agencies. In accordance with 40 CFR 35.145(a), the Regional Administrator may provide air pollution control agencies up to three-fifths of the approved costs of implementing programs for the prevention and control of air pollution. CAA section 105 grants require two types of cost share requirements, a match requirement and an MOE requirement. An eligible agency must meet a minimum 40% match. In addition, to remain eligible for CAA section 105 grants, an eligible agency must meet an MOE requirement under section 105(c)(1) of the CAA, 42 U.S.C. 7405(c)(1).

Program activities relevant to the match consist of both recurring and non-recurring (unique, one-time only) expenses. The MOE provision requires that a state or local agency spend at least the same dollar level of funds as it did in the previous grant year, but only for the costs of recurring activities. Specifically, section 105(c)(1) of the CAA, 42 U.S.C. 7405(c)(1), provides that, ''No agency shall receive any grant under this section during any fiscal year when its expenditures of non-Federal funds for recurrent expenditures for air pollution control programs [maintenance of effort or MOE level] will be less than its expenditures were for such programs during the preceding fiscal year.'' The EPA's implementing regulations at 40 CFR 35.146(a) reiterate the CAA section 105(c)(1) MOE requirement.

Although the PRDNER has successfully completed a portion of its Fiscal Year 2019 air pollution control program, PRDNER has faced challenges that have impacted its ability to meet the statutory MOE requirement for its Fiscal Year 2019 CAA section 105 grant. By letter to the EPA dated May 15, 2023, PRDNER explained that compliance with the MOE has been a challenge due to natural events that affected Puerto Rico such as hurricanes and earthquakes and the interruptions to the operations of the Government of Puerto Rico due to the COVID–19 pandemic. The restrictions imposed by the Department of Health to prevent or reduce the risk of COVID–19 exposure affected PRDNER's performance of grant workplan tasks. These factors combined with fiscal constraints and the lack of sufficient human resources to complete the grant workplan tasks created an MOE shortfall. Since PRDNER did not satisfy the statutory requirement for the maintenance of effort for Fiscal Year 2019, EPA intends to revoke PRDNER's Fiscal Year 2019 CAA section 105 grant. Pursuant to section 105(e) of the CAA, the EPA is providing prior notice of its intent to revoke PRDNER's Fiscal Year 2019 CAA section 105 grant. The proposed administrative action does not otherwise impact the air pollution control program already carried out by PRDNER during Fiscal Year 2019, which ended on September 30, 2019.

This notice constitutes a request for public comment and an opportunity for public hearing as required by CAA section 105(e) and EPA's implementing regulations at 40 CFR 35.148(b). All written comments received by August 30, 2023 on this proposal will be considered. EPA will conduct a public hearing on this proposal if EPA finds, based on written requests for a public hearing, that the issues raised are substantial or a significant degree of public interest in this proposal has been expressed; written requests for a hearing must be received by EPA at the address above by August 30, 2023. If no written request for a hearing is received or if EPA determines that the issues raised are insubstantial or no significant degree of public interest in this proposed action has been expressed, EPA will proceed to the final action on this grant.

Lisa Garcia,

Regional Administrator, Region 2.

[FR Doc. 2023–16114 Filed 7–28–23; 8:45 am]

BILLING CODE 6560–50–P

FARM CREDIT ADMINISTRATION

Sunshine Act Meetings

TIME AND DATE: 10:00 a.m., Thursday, August 10, 2023.

PLACE: You may observe 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*, select ''Newsroom,'' then select ''Events.'' From there, access the linked ''Instructions for board meeting visitors'' and complete the described registration process.

STATUS: This meeting will be open to the public.

MATTERS TO BE CONSIDERED:

The following matters will be considered:

- Approval of Minutes for July 13, 2023
- Annual Report on the Farm Credit System's Young, Beginning, and Small Farmers and Ranchers Mission Performance

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. 2023–16370 Filed 7–27–23; 4:15 pm]

BILLING CODE 6705–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Sunshine Act Meetings

TIME AND DATE: 11:16 a.m. on Thursday, July 27, 2023.

PLACE: The meeting was held in the Board Room located on the sixth floor of the FDIC Building located at 550 17th Street NW, Washington, DC.

STATUS: Closed.

MATTERS TO BE CONSIDERED: The Board of Directors of the Federal Deposit Insurance Corporation met to consider matters related to the Corporation's supervision, corporate, and resolution activities. In calling the meeting, the Board determined, on motion of Vice Chairman Travis J. Hill, seconded by Director Jonathan P. McKernan, and concurred in by Director Rohit Chopra (Director, Consumer Financial Protection Bureau), Director Michael J. Hsu (Acting Comptroller of the Currency), and Chairman Martin J. Gruenberg, that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B).

CONTACT PERSON FOR MORE INFORMATION: Requests for further information concerning the meeting may be directed

to Debra A. Decker, Executive Secretary of the Corporation, at 202–898–8748.

Dated this the 27th day of July, 2023.

Federal Deposit Insurance Corporation.

James P. Sheesley,

Assistant Executive Secretary.

[FR Doc. 2023–16306 Filed 7–27–23; 4:15 pm]

BILLING CODE 6714–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Health Statistics

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS). This meeting is open to the public. Time will be available for public comment.

DATES: The meeting will be held on September 14, 2023, from 11 a.m. to 5 p.m., EDT.

ADDRESSES: Instructions to access the live meeting broadcast will be posted here: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm.*

FOR FURTHER INFORMATION CONTACT: Rebecca Hines, M.H.S., Designated Federal Officer, Board of Scientific Counselors, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Mailstop P–08, Hyattsville, Maryland 20782. Telephone: (301) 458–4715; Email: *RSHines@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Board of Scientific Counselors, National Center for Health Statistics (BSC, NCHS) is charged with providing advice and making recommendations to the Secretary, Department of Health and Human Services; the Director, Centers for Disease Control and Prevention; and the Director, National Center for Health Statistics, regarding the scientific and technical program goals and objectives, strategies, and priorities of NCHS.

Matters to Be Considered: The meeting agenda will include an update from the NCHS Director; an update on the role of artificial intelligence and machine learning in NCHS programs; an update from NCHS on long-term health care data collection; an update from NCHS on the National Health Interview Survey; and discussion regarding current issues and topics. The Board will reserve time for public comment at the end of the day. Meeting times and agenda topics are subject to change as priorities dictate.

Meeting Information: Please visit the BSC, NCHS website for details: *https://www.cdc.gov/nchs/about/bsc/bsc_meetings.htm.* Further information and the meeting agenda will be available on the website, including any agenda updates and the instructions for accessing the live meeting broadcast.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–16103 Filed 7–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of closed meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC or Board). This meeting is partially open to the public.

DATES: The meeting will be held on September 20, 2023. The first session of the day will be held from 1 p.m. to 2:30 p.m., EDT (OPEN), and the second session will be held from 2:30 p.m. to 4:30 p.m., EDT (CLOSED). The public comment period will be at the end of the open session of the meeting, from 2:10 p.m. to 2:25 p.m., EDT.

ADDRESSES: Webinar, Atlanta, Georgia. All participants must register by using the following link to attend the open session: *https://cdc.zoomgov.com/webinar/register/WN_6fMCRBe2SzmPnasMtiyF_Q.*

FOR FURTHER INFORMATION CONTACT: Christopher R. Harper, Ph.D., Designated Federal Officer, Board of Scientific Counselors, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway, NE, Mailstop S–1069, Atlanta, Georgia 30341. Telephone: (404) 718–8330; Email: *ncipcbsc@cdc.gov.*

SUPPLEMENTARY INFORMATION: Portions of the meeting referenced above will be closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), title 5, U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, pursuant to 5 U.S.C. 1009 (Pub. L. 92–463, as amended).

Purpose: The Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC or Board) will: (1) conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes and strategies related to the prevention of injury and violence; (2) assist States and other entities in preventing intentional and unintentional injuries, and to promote health and well-being; and (3) make recommendations of grants and cooperative agreements for research and prevention activities related to injury and violence. The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities and reviews progress toward injury and violence prevention. The Board also provides advice on the appropriate balance of intramural and extramural research and provides guidance on the needs, structure, progress, and performance of intramural programs. Further, the Board provides guidance on extramural scientific program matters. Additionally, the Board provides second-level scientific and programmatic review of applications for research grants, cooperative agreements, and training grants related to injury and violence prevention, and recommends approval of projects that merit further consideration for funding support. Finally, the Board also recommends areas of research to be supported by contracts and cooperative agreements and provides concept reviews of program proposals and announcements.

Matters to be Considered: The open session of the meeting will include a discussion on the updated Intimate Partner Violence Prevention Research Priorities. The closed session of the meeting will focus on the Secondary Peer Review of extramural research grant applications received in response to one (1) Notice of Funding Opportunity: RFA–CE–24–001—''Grants for Injury Control Research Centers.'' Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–16104 Filed 7–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to CDC's Advisory Committee to the Director Data and Surveillance Workgroup

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Advisory Committee to the Director Data and Surveillance Workgroup (DSW). The DSW consists of approximately 15 members who are experts in fields associated with public health science and practice; policy development, analysis, and implementation; and surveillance and informatics.

DATES: Nominations for membership on the DSW must be received no later than August 30, 2023. Late nominations will not be considered for membership.

ADDRESSES: All nominations (cover letters and curriculum vitae) should be emailed to *DSWACD@cdc.gov* with the subject line: ''Nomination for CDC ACD DSW Workgroup.''

FOR FURTHER INFORMATION CONTACT: Agnes Warner, MPA, Office of Public Health Data, Surveillance, and Technology, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, Georgia 30329–4027. Telephone: (404) 639–3372; Email: *DSWACD@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The purpose of the Advisory Committee to the Director, Centers for Disease Control and Prevention (ACD, CDC) is to (1) make recommendations to the Director regarding ways to prioritize the activities of the agency in alignment with the CDC Strategic Plan required under section 305(c); H.R. 2617–1252; (2) advise on ways to achieve or improve performance metrics in relation to the CDC Strategic Plan, and other relevant metrics, as appropriate; (3) provide advice and recommendations on the development of the Strategic Plan, and any subsequent updates, as appropriate; (4) advise on grants, cooperative agreements, contracts, or other transactions, as applicable; (5) provide other advice to the Director, as requested, to fulfill duties under sections 301 and 311; and (6) appoint subcommittees. The ACD, CDC consists of up to 15 non-federal members, including the Chair, knowledgeable in areas pertinent to the CDC mission, such as health policy, public health, global health, preparedness, preventive medicine, the faith-based and community-based sector, and allied fields.

Purpose: The purpose of the ACD, CDC Data and Surveillance Workgroup (DSW) is to provide input to the Committee on agency-wide activities related to the scope and implementation of CDC's data modernization strategy across the agency, ultimately playing a key role in the agency's work with public health, healthcare, and academic and private sector partners and with the promotion of equity. The DSW membership consists of approximately 15 members. It is co-chaired by two current ACD, CDC Special Government Employees. The DSW co-chairs will present their findings, observations, and work products at one or more ACD, CDC meetings for discussion, deliberation, and decisions (final recommendations to CDC).

Nomination Criteria: DSW members will serve terms ranging from six months to one year and be required to attend DSW meetings approximately 1–2 times per month (virtually or in person), and contribute time in between meetings for research, consultation, discussion, and writing assignments.

Nominations are being sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishments of the committee's/workgroup's objectives. Nominees will be selected based on expertise in the fields of public health science and practice; public health preparedness and response; public health policy development, analysis, and implementation; public health surveillance and informatics; artificial intelligence; data analysis, data science, and forecasting; health information technology; and healthcare delivery from jurisdictional government agencies, non-government organizations, academia, and the private sector. To ensure a diverse workgroup composition, nominees with front line and field experience at the local, state, tribal, and territorial levels are encouraged to apply. This includes nominees with experience working for, and with, community-based organizations and other non-profit organizations. Federal employees will not be considered for membership. Selection of members is based on candidates' qualifications to contribute to the accomplishment of the DSW's objectives.

HHS policy stipulates that membership be balanced in terms of points of view represented and the workgroup's function. Appointments shall be made without discrimination based on age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Interested candidates should submit the following items:

- A one-half to one-page cover letter that includes your understanding of, and commitment to, the time and work necessary; one to two sentences on your background and experience; and one to two sentences on the skills/perspective you would bring to the DSW.
- Current curriculum vitae which highlights the experience and work history being sought relevant to the criteria set forth above, including complete contact information (telephone numbers, mailing address, email address).

Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–16102 Filed 7–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Center for Health Statistics, ICD–10 Coordination and Maintenance Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: The Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), Classifications and Public Health Data Standards Staff, announces the following meeting of the ICD–10 Coordination and Maintenance (C&M) Committee. This meeting is open to the public, limited only by the number of audio lines available. Online Registration is required.

DATES: The meeting will be held on September 12, 2023, from 9 a.m. to 5 p.m., EDT, and September 13, 2023, from 9 a.m. to 5 p.m., EDT.

ADDRESSES: This is a virtual meeting. Register in advance at *https://cms.zoomgov.com/webinar/register/WN_lWLKuwKzQU6iJdvcDvXhdA.* After registering, you will receive a confirmation email containing information about joining the meeting. Further information will be provided on each of the respective web pages when it becomes available. For CDC, NCHS: *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm.* For the Centers for Medicare & Medicaid Services, Department of Health and Human Services: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.*

FOR FURTHER INFORMATION CONTACT: Traci Ramirez, Medical Classification Specialist, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782–2064. Telephone: (301) 458–4454; Email: *TRamirez@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The ICD–10 Coordination and Maintenance (C&M) Committee is a public forum for the presentation of proposed modifications to the International Classification of Diseases, Tenth Revision, Clinical Modification (CM) and ICD–10 Procedure Coding System (PCS).

Matters to be Considered: The tentative agenda will include discussions on the ICD–10–CM and ICD–10–PCS topics listed below. Agenda items are subject to change as priorities dictate. Please refer to the posted agenda for updates one month prior to the meeting.

ICD–10–PCS Topics:

1. Administration of Iodine (131I) Apamistamab **
2. Irreversible Electroporation for Cardiac Ablation **
3. Computer-aided Anesthesia and Oxygen Delivery System ***
4. Sub-epidermal Moisture Sensor **
5. Insertion of Palladium-103 Radioactive Implant *
6. Implantation of Bone Void Filler ***
7. Section X Updates
8. Addenda and Key Updates *

* Request is for an April 1, 2024, implementation date.

** Request is for an April 1, 2024, implementation date, and the requestor intends to submit a new technology add-on payment (NTAP) application for FY 2025 consideration.

*** Requestor intends to submit an NTAP application for FY 2025 consideration.

Presentations for procedure code requests are conducted by both the requestor and the Centers for Medicare & Medicaid Services (CMS) during the C&M Committee meeting. Discussion from the requestor generally focuses on the clinical issues for the procedure or technology, followed by the proposed coding options from a CMS analyst. Topics presented may also include requests for new procedure codes that relate to a new technology add-on payment (NTAP) policy request.

CMS has modified the approach for presenting the new NTAP-related ICD–10–PCS procedure code requests that involve the administration of a therapeutic agent. For the September 12–13, 2023, ICD–10 C&M Committee meeting, consistent with the requirements of section 1886(d)(5)(K)(iii) of the Social Security Act, applicants submitted requests to create a unique procedure code to describe the administration of a therapeutic agent, such as the option to create a new code in Section X within the ICD–10–PCS procedure code classification. CMS will initially display only those meeting materials associated with the NTAP-related ICD–10–PCS procedure code requests that involve the administration of a therapeutic agent on the CMS website in August 2023 at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.*

The NTAP-related ICD–10–PCS procedure code request that involves the administration of a therapeutic agent is:

Administration of Iodine (131I) Apamistamab **

** Request is for an April 1, 2024, implementation date, and the requestor intends to submit an NTAP application for FY 2025 consideration.

This topic will not be presented during the September 12–13, 2023, meeting. CMS will solicit public comments regarding any clinical questions or coding options included for this procedure code topic in advance of the meeting continuing through the end of the respective public comment periods. Members of the public should send any questions or comments to the CMS mailbox at: *ICDProcedureCodeRequest@cms.hhs.gov.*

CMS intends to post a question-and-answer document in advance of the meeting to address any clinical or coding questions that members of the public may have submitted. Following the conclusion of the meeting, CMS will post an updated question-and-answer document to address any additional clinical or coding questions that members of the public may have submitted during the meeting that CMS was not able to address or that were submitted after the meeting.

The NTAP-related ICD–10–PCS procedure code requests that do not involve the administration of a therapeutic agent and all non-NTAP-related procedure code requests will continue to be presented during the virtual meeting on September 12, 2023, consistent with the standard meeting process.

CMS will make all meeting materials and related documents available at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials.* Any inquiries related to the procedure code topics scheduled for the September 12–13, 2023, ICD–10 C&M Committee meeting that are under consideration for

April 1, 2024, or October 1, 2024, implementation should be sent to the CMS mailbox at: *ICDProcedureCodeRequest@cms.hhs.gov.*

ICD–10–CM Topics:

1. Abnormal Anti-cyclic Citrullinated Peptide Antibody and/or Rheumatoid Factor Without Current or Prior Clinical Diagnosis of Rheumatoid Arthritis
2. Adverse Effects of Immune Checkpoint Therapy
3. Anal Fistula
4. Baked Egg Tolerance
5. Baked Milk Tolerance
6. Duffy Phenotype
7. Flank Anatomical Specificity
8. Gulf War Illness
9. Hyperoxaluria
10. Injection Drug Use
11. Lymphoma in Remission
12. Post-exertional Malaise
13. Usher Syndrome
14. Addenda

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–16105 Filed 7–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–9893–N]

Meeting Date for Ground Ambulance and Patient Billing (GAPB) Advisory Committee—August 16, 2023

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: This notice announces the second public meeting of the Ground Ambulance and Patient Billing (GAPB) Advisory Committee on August 16, 2023. The GAPB Advisory Committee will make recommendations with respect to the disclosure of charges and fees for ground ambulance services and insurance coverage, consumer protection and enforcement authorities of the Departments of Labor, Health and Human Services, and the Treasury (the Departments) and relevant States, and the prevention of balance billing to consumers. The recommendations will address options, best practices, and identified standards to prevent instances of balance billing; steps that can be taken by State legislatures, State insurance regulators, State attorneys general, and other State officials as appropriate, consistent with current legal authorities regarding consumer protection; and, legislative options for Congress to prevent balance billing.

DATES:

Virtual Meeting Date: The GAPB Advisory Committee will hold a virtual meeting on Wednesday, August 16, 2023, from 9:30 a.m. to 5:30 p.m., Eastern Daylight Time.

Registration Link: The virtual meeting will be open to the public and held via the Zoom webinar platform. Virtual attendance information will be provided upon registration. To register for this virtual meeting visit: *https://priforum.zoomgov.com/webinar/register/WN_fRPS8zNkQbOl1GZux_M-eA.* Attendance is open to the public subject to any technical or capacity limitations.

Deadline for Registration: All individuals who plan to attend the virtual public meeting must register to attend. The deadline to register for the public meeting is Tuesday, August 15, 2023. Interested parties are encouraged to register as far in advance of the meeting as possible. A detailed agenda and materials will be available prior to the meeting on the GAPB Advisory Committee website at: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.*

A recording and a summary of the meeting will be made available on the GAPB Advisory Committee website within 45 calendar days after the meeting.

ADDRESSES: *Virtual Meeting Location:* The August 16, 2023, public meeting will be held virtually via Zoom only.

FOR FURTHER INFORMATION CONTACT: Shaheen Halim, CMS, by phone (410) 786–0641 or via email at gapbadvisorycommittee@*cms.hhs.gov.*

Press inquiries may be submitted by phone at (202) 690–6145 or via email at *press@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 117(a) of the No Surprises Act, enacted as part of the Consolidated Appropriations Act, 2021, div. BB, tit. I, Public Law 116–260 (Dec. 27, 2020), requires the Secretaries of the Departments of Labor, the Department of Health and Human Services (HHS), and the Treasury (collectively, the Departments) to establish and convene an advisory committee for the purpose of reviewing options to improve the disclosure of charges and fees for ground ambulance services, better inform consumers of insurance options for such services, and protect consumers from balance billing. The GAPB Advisory Committee is governed by the provisions of the Federal Advisory Committee Act (FACA), Public Law 92–463 (Oct. 6, 1972), as amended, 5 U.S.C. app. 2. The GAPB Advisory Committee held its first meeting on May 2, 2023 and May 3, 2023. Information on past and current Committee activity can be found at: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.*

II. Advisory Committee Membership Roster

On November 23, 2021, HHS published a Notice of Charter and Invitation for Member Nominations in the **Federal Register** for the GAPB Advisory Committee (86 FR 66565 through 66566). The Departments evaluated the nominees for alignment with the membership categories required under section 117 of the No Surprises Act, their professional qualifications, recognition by the ground ambulance and emergency medical services community, years of relevant experience, experience with State or Federal committees on related issues, and expertise in subject matter to be addressed by the committee. The Departments also considered membership balance as required by the FACA, and as appropriate to address health equity issues pertaining to ground ambulance consumer balance billing, and ground ambulance services in underserved communities. On December 16, 2022, HHS published a **Federal Register** notice, announcing the 17 Members of the GAPB Advisory Committee (87 FR 77122 through 77123). A subsequent update to the Committee Roster was published on April 14, 2023 (88 FR 23046).

The 17 Members of the GAPB Advisory Committee are as follows:

- Asbel Montes—Committee Chairperson; Additional Representative

determined necessary and appropriate by the Secretaries.

- Ali Khawar—Secretary of Labor's Designee.
- Carol Weiser—Secretary of the Treasury's Designee.
- Rogelyn McLean—Secretary of Health and Human Services' Designee.
- Gamunu Wijetunge—Department of Transportation—National Highway Traffic Safety Administration.
- Suzanne Prentiss—State Insurance Regulators.
- Adam Beck—Health Insurance Providers.
- Patricia Kelmar—Consumer Advocacy Groups.
- Gary Wingrove—Patient Advocacy Groups.
- Ayobami Ogunsola—State and Local Governments.
- Ritu Sahni—Physician specializing in emergency, trauma, cardiac, or stroke.
- Peter Lawrence—State Emergency Medical Services Officials.
- Shawn Baird—Emergency Medical Technicians, Paramedics, and Other Emergency Medical Services Personnel.
- Edward Van Horne—Representative of Various Segments of the Ground Ambulance Industry.
- Regina Godette-Crawford—Representative of Various Segments of the Ground Ambulance Industry.
- Rhonda Holden—Representative of Various Segments of the Ground Ambulance Industry.
- Loren Adler—Additional Representative determined necessary and appropriate by the Secretaries

The GAPB Advisory Committee Roster is also available on the GAPB Advisory Committee website at: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.* All future updates to the Advisory Committee Roster will be published on this website.

III. Meeting Agenda

The second public meeting of the GAPB Advisory Committee will take place on August 16, 2023. During this meeting, the Committee will review and discuss preliminary findings and recommendations from its two subcommittees. The agenda will cover the following topics:

- Preliminary findings and recommendations of the GAPB Advisory Committee's subcommittee on Network Adequacy and Cost/Payment Structures.
- Preliminary findings and recommendations of the GAPB Advisory Committee's subcommittee on Public/Consumer Disclosures and Protections.

A more detailed agenda and materials will be made available prior to the meeting on the GAPB Advisory Committee website (listed previously).

Anticipated Dates for Future GAPB Advisory Committee Meetings

The Centers for Medicare & Medicaid Services (CMS) expects to convene future GAPB Advisory Committee Meetings on the following dates: October 31, 2023 and November 1, 2023. Agendas and registration information for future meeting dates will be published in the **Federal Register** and on the GAPB Advisory Committee website closer to the anticipated meeting dates, which are subject to change.

IV. Public Participation

The August 16, 2023, GAPB Advisory Committee meeting will be open to the public. Attendance may be limited due to virtual meeting constraints. Interested parties are encouraged to register as far in advance of the meeting as possible. To register for the meeting visit: *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.* CMS is committed to providing equal access to this meeting for all participants and to ensuring section 508 compliance. Closed captioning will be provided. To request alternative formats or services because of a disability, such as sign language interpreters or other ancillary aids, refer to the appropriate contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

V. Submitting Written Comments

Members of the public may submit written comments for consideration by the Committee at any time via email to *gapbadvisorycommittee@cms.hhs.gov.* Additionally, members of the public will have the opportunity to submit comments during the August 16, 2023, virtual meeting through the chat feature of the Zoom webinar platform. Members of the public are encouraged to submit lengthy written comments on topics discussed during the meeting to the email address in the **DATES** section by September 5, 2023, to ensure timely consideration by the Committee.

VI. Viewing Documents

You may view the documents discussed in this notice at *https://www.cms.gov/regulations-guidance/advisory-committees/advisory-committee-ground-ambulance-and-patient-billing-gapb.*

The Administrator of CMS, Chiquita Brooks-LaSure, having reviewed and approved this document, authorizes Evell J. Barco Holland, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Evell J. Barco Holland,

Federal Register Liaison, Centers for Medicare & Medicaid Services.

[FR Doc. 2023–16146 Filed 7–28–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2459]

Agency Information Collection Activities; Proposed Collection; Comment Request; Product Jurisdiction and Combination Products

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 product jurisdiction and combination product regulations.

DATES: Either electronic or written comments on the collection of information must be submitted by September 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 September 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–2459 for ''Product Jurisdiction and Combination Products.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: 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, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed extension of the existing 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.

Product Jurisdiction and Combination Products—21 CFR Parts 3 and 4

OMB Control Number 0910–0523—Extension

This information collection helps support implementation of statutory requirements that govern product jurisdiction and combination products. Congress expressly directed FDA to assign combination products to the appropriate Agency component for regulation as set forth in section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353(g)). Congress also expressly directed FDA to determine the classification of a product as a drug, biological product, device, or combination product, or the component of the Agency that will regulate the product, as applicable, in response to a request submitted under section 563 of the FD&C Act (21 U.S.C. 360bbb–2).

Regulations in 21 CFR part 3 provide for product classification determinations and FDA designation on which Agency component will have primary jurisdiction for any drug, device, biological, or combination product, where such jurisdiction is unclear or in dispute. These determinations are made by our Office of Combination Products (OCP) upon receiving Requests for Designation (RFDs). We maintain a web page that includes contact and resource information pertaining to the RFDs process at *https://www.fda.gov/combination-products/jurisdictional-information.* As communicated on our web page, FDA welcomes comments from interested stakeholders on issues pertaining to OCP and encourages medical product developers to contact us if they are uncertain about the classification or assignment of their products and with questions regarding premarket or postmarket considerations for combination products. A dedicated mailbox is established at *combination@fda.gov.*

Similar to the RFD process, we have established the Pre-RFD process for sponsors to obtain preliminary, nonbinding feedback regarding medical product classification and assignment. Although Forms FDA 5003, 5004, and 5005 (pre-request and request for designation forms) were previously developed to facilitate information collection for Pre-RFDs and RFDs, we have more recently issued the following Agency guidance documents to provide instruction and recommendations to respondents regarding the submission of RFDs and Pre-RFDs.

• The guidance document entitled, ''How to Write a Request for Designation'' (April 2011), provides instruction regarding the information that needs to be submitted to OCP in an RFD as described in 21 CFR 3.7. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-write-request-designation-rfd.*

• The guidance document entitled ''How to Prepare a Pre-Request for Designation,'' (February 2018) was developed to assist sponsors in obtaining a preliminary, non-binding assessment regarding the classification and assignment of products from OCP through the Pre-RFD process. The guidance explains the Pre-RFD process and helps a sponsor understand the type of information to provide in a Pre-RFD submission. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/how-prepare-pre-request-designation-pre-rfd.*

• This information collection also includes burden associated with Combination Product Agreement Meetings (CPAM) requests. The guidance document entitled, ''Requesting FDA Feedback on Combination Products,'' (December 2020) was developed to discuss ways in which combination product sponsors can obtain feedback from FDA on scientific and regulatory questions and to describe best practices for FDA and sponsors when interacting on these topics. The guidance is available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/requesting-fda-feedback-combination-products.*

The guidance documents were issued consistent with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

The information collection also includes regulations in 21 CFR part 4 that govern current good manufacturing practice requirements and postmarketing safety requirements for combination products. We expect, however, that burden attendant to the associated recordkeeping, reporting, and/or disclosure activities is already accounted for in approved information collections that apply to drug, device, and/or biologic products specifically and respectively. Therefore, we do not ascribe separate burden in this information collection request for the activities generated by these requirements.

Respondents to the information collection are sponsors of medical products, including combination products. Based on submissions received by OCP during fiscal years 2020, 2021, and 2022, we account for 135 respondents annually.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3.7; request for designation (RFD)	55	1	55	24	1,320
Pre-RFD submissions	77	1	77	24	1,848
CPAM requests	3	1	3	25	75
Total					3,243

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden reflects a decrease in the number of respondents (four respondents) and a corresponding decrease in total hours (96 hours). Based on a recent evaluation of CPAM requests received from each product center in fiscal years 2020, 2021, and 2022, our estimated annual burden for CPAM requests remains unchanged.

Dated: July 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16150 Filed 7–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2707]

Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption From Preemption

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 the information collection provisions of our reporting requirements contained in FDA regulations governing state petitions for exemption from preemption.

DATES: Either electronic or written comments on the collection of information must be submitted by September 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 September 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–2707 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; State Petitions for Exemption from Preemption.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

State Petitions for Exemption From Preemption—21 CFR 100.1

OMB Control Number 0910–0277—Extension

This information collection supports FDA regulations. Under section 403A(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 343–1(b)), States may petition FDA for exemption from Federal preemption of State food labeling and standard-of-identity requirements. Section 100.1(c) (21 CFR 100.1(c)) provides prerequisites a petition must satisfy for an exemption from preemption. Section 100.1(d) sets forth the information a State is required to submit in such a petition. The petition may be submitted either as: (1) an original and one copy or (2) an original and a computer-readable disk containing the petition. Contents of the disk should be in a standard format. The petition must be submitted to the Dockets Management Staff at the address provided in the section ''Written/Paper Submissions.'' The information required under § 100.1 enables FDA to determine whether the State food labeling or standard-of-identity requirement satisfies the criteria of section 403A(b) of the FD&C Act for granting exemption from Federal preemption.

Description of Respondents: The respondents to this collection of information are State and local governments who regulate food labeling and standards of identity.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
100.1; petition for exemption from preemption	1	1	1	40	40

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The reporting burden for § 100.1 is minimal because petitions for exemption from preemption are seldom submitted by States. In the next 3 years, we estimate that one or fewer petitions will be submitted annually.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16151 Filed 7–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Heart, Lung, and Blood Institute Special Emphasis Panel, Opportunities for Collaborative Research at the NIH Clinical Center (U01), August 24, 2023, 2:00 p.m. to August 24, 2023, 4:00 p.m., National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD, 20892 which was published in the **Federal Register** on July 19, 2023, FR Doc 2023–15228, 88 FRN 46172.

The National Heart, Lung, and Blood Institute Special Emphasis Panel meeting is being amended due to a change of the meeting date and time formats. The meeting will be held on September 8, 2023, from 11:00 a.m. to 1:00 p.m. This meeting will be a video-assisted and closed to the public.

Dated: July 25, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16133 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Arthritis and Musculoskeletal and Skin Diseases Advisory Council.

This will be a hybrid meeting held in-person and virtually and will be open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting can be accessed from the NIH Videocast at the following link: *https://videocast.nih.gov/.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Arthritis and Musculoskeletal and Skin Diseases Advisory Council

Date: August 29, 2023

Open: 9:00 a.m. to 1:00 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 6C Room A & B, 31 Center Drive, Bethesda, MD 20892 (Hybrid Meeting)

Closed: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Building 31, 6C Room A & B, 31 Center Drive, Bethesda, MD 20892

Contact Person: Darren D. Sledjeski, Ph.D. Director, Division of Extramural Activities (DEA), National Institute of Arthritis and, Musculoskeletal and Skin Diseases, 6701 Democracy BLVD., Bethesda, MD 20892, (301) 451–7766, *darren.sledjeski@nih.gov*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has procedures at *https://www.nih.gov/about-nih/visitor-information/campus-access-security* for entrance into on-campus and off-campus facilities. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors attending a meeting on campus or at an off-campus federal facility will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *https://www.niams.nih.gov/about/working-groups/advisory-council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: July 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16135 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; Phase 2 Clinical Trials in Neurology.

Date: August 14, 2023.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Iqbal Sayeed, Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS/NIH NSC, 6001 Executive Blvd., Suite 3208, MSC 9529, Rockville, MD 20852, 301–496–9223, *iqbal.sayeed@nih.gov*.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS.)

Dated: July 25, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16134 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995 to provide opportunity for public comment on proposed data collection projects, the Office of Clinical Research Education, Collaboration, and Outreach (OCRECO), Office of the Director (OD), National Institutes of Health, will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Dr. Anne Zajicek, M.D., Pharm.D., Program Director, Office of Clinical Research Education, Collaboration, and Outreach, NIH Office of the Director, Building 1, Room 201, MSC–0155, Bethesda, Maryland 20892 or call non-toll-free number (301) 480–9913 or email your request, including your address to: *zajiceka@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

SUPPLEMENTARY INFORMATION: Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires: written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimizes the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Proposed Collection Title: Application and Impact of Clinical Research Training on Healthcare Professionals in Academia and Clinical Research, 0925–0764, exp., date 02/28/2026, Revision Office of Clinical Research Education and Collaboration Outreach (OCRECO), National Institutes of Health (NIH), Office of the Director (OD).

Need and Use of Information Collection: The purpose of this revision is to: update the name of the office responsible for these on-line training programs (from Office of Clinical Research to Office of Clinical Research Education and Collaboration Outreach); revise the course evaluation survey questions; add an additional on-line course, ''Ethical and Regulatory Aspects of Clinical Research''; change the course opening and close dates from Oct–June to Sept–July. The survey will continue to assess the long-term impact and outcomes of clinical research training programs provided by the newly formed Office of Clinical Research Education, Collaboration, and Outreach (previously the Office of Clinical Research) located in the NIH Office of the Director (OD) over a ten-year follow-up period. The information received from respondents will provide insight on the following: impact of the courses on (a) promotion of professional competence, (b) research productivity and independence, and (c) future career development within clinical, translational, and academic research settings. These surveys will provide preliminary data and guidance in (1) developing recommendations for collecting outcomes to assess the effectiveness of the training courses, and (2) tracking the impact of the curriculum on participants' ability to perform successfully in academic, non-academic, research, and non-research settings.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 820.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Estimated number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
OCRECO Learning Portal Registration (Attachment 1)	Healthcare Professionals	2000	1	5/60	167
	Students	1000	1	5/60	83
	General Public	500	1	5/60	42
IPPCR Lecture Evaluation (Attachment 2)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
IPPCR Final Course Evaluation(Attachment 4)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Form name	Type of respondents	Estimated number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hours
	General Public	250	1	5/60	21
PCP Lecture Evaluation (Attachment 3)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
PCP Final Course Evaluation (Attachment 5)	Healthcare Professionals	750	1	5/60	63
	Students	500	1	5/60	42
	General Public	250	1	5/60	21
NIH Summer Course in Clinical and Translational Research Course Evaluation (Attachment 6).	Healthcare Professionals	20	1	5/60	2
Sabbatical in Clinical Research Management Course Evaluation (Attachment 7).	Healthcare Professionals	20	1	5/60	2
Ethical and Regulatory Aspects of Clinical Research (Asynchronous/Online) Course (Attachment 8).	Healthcare Professionals	100	1	5/60	8
	Students	50	1	5/60	4
	General Public	100	1	5/60	8
Total			9,790		820

Dated: July 25, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

[FR Doc. 2023–16184 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Human Genome Research Institute; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Human Genome Research.

This is a hybrid meeting held in-person and virtually and is open to the public as indicated below. Individuals who plan to attend in-person or view the virtual meeting and need special assistance or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will be videocast and can be accessed from *https://www.genome.gov/about-nhgri/Institute-Advisors/National-Advisory-Council-for-Human-Genome-Research.*

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Human Genome Research.

Date: September 18–19, 2023.

Closed: September 18, 2023, 9:00 a.m. to 10:00 a.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Open: September 18, 2023, 10:30 a.m. to 6:30 p.m.

Agenda: Report of Institute Director and Institute Staff.

Place: National Human Genome Research Institute, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Closed: September 19, 2023, 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Human Genome Research Institute, National Institutes of Health, 6700B Rockledge Drive, Suite 1100, Bethesda, MD 20892.

Contact Person: Rudy O. Pozzatti, Ph.D., Scientific Review Officer, Scientific Review Branch, National Human Genome Research Institute, 6700B Rockledge Drive, Suite 1100, Rockville, MD 20892, (301) 402–0838, *pozzattr@mail.nih.gov.*

Any interested person may file written comments with the committee within 15 days after the meeting by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.genome.gov/council,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.172, Human Genome Research, National Institutes of Health, HHS)

Dated: July 26, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–16147 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Generic Clearance for NIH Citizen Science and Crowdsourcing Projects (Office of the Director)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below.

DATES: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: Desk Officer for NIH.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of

the data collection plans and instruments, contact: Mikia Currie, Chief, Project Clearance Branch, Office of Policy and Extramural Research Administration, Office of the Director, Office of Extramural Research, NIH, 6705 Rockledge Drive, Bethesda, Maryland 20892, MSC 7980, or call non-toll-free number (301) 435–0941 or email your request, including your address to: *ProjectClearanceBranch@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** on February 14th, 2023, page 9527–9528 (88 FR 9527) and allowed 60 days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The Project Clearance Branch, Office of Policy and Extramural Research Administration, Office of the Director, Office of Extramural Research, National Institutes of Health (NIH), may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid Office of Management and Budget (OMB) control number.

In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, NIH has submitted to OMB a request for review and approval of the information collection listed below.

Proposed Collection: Generic Clearance for NIH Citizen Science and Crowdsourcing Projects—0925–0766—07/31/2023 Extension, Project Clearance Branch (PCB), Office of Policy and Extramural Research Administration (OPERA), Office of the Director (OD), Office of Extramural Research (OER), National Institutes of Health (NIH).

Need and Use of Information Collection: Projects under this generic clearance will continue to allow Agency researchers and program staff to test ideas more quickly, respond to the project's needs as they evolve, and incorporate feedback from participants for flexible, innovative research methods. The purpose of this information collection is to:

- Accelerate scientific research
- Increase cost-effectiveness to maximize the return on taxpayer dollars
- Address societal needs
- Provide hands-on learning in STEM education
- Connect members of the public directly to federal science missions and each other
- Identify and disseminate resources more broadly to the public, on the Institutes' and Centers' websites, and/or
- Collect information for agency internal use to improve scientific practices and/or assist in scientific reviews

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 18,584.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of collection	Number of respondents	Number of responses per respondent	Time per response (in hours)	Total hours
Call for Nominations/Resources	1,000	1	10/60	167
Recommendations of scientific reviewers	1,000	1	5/60	83
Request for Population Characteristics	20,000	1	5/60	1,667
Repository of Tools and Best Practices	100,000	1	10/60	16,667
Total	122,000			18,584

Dated: July 25, 2023.

Tara A. Schwetz,

Acting Principal Deputy Director, National Institutes of Health.

[FR Doc. 2023–16185 Filed 7–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Meeting of the Substance Abuse and Mental Health Services Administration National Advisory Council

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given for the meeting on August 31, 2023, of the Substance Abuse and Mental Health Services Administration National Advisory Council (SAMHSA NAC). The meeting is open to the public and can also be accessed virtually. Agenda with call-in information will be posted on the SAMHSA website prior to the meeting at: *https://www.samhsa.gov/about-us/advisory-councils/meetings.* The meeting will include, but not be limited to, remarks from the Assistant Secretary for Mental Health and Substance Use; consideration and approval of the meeting minutes of April 27, 2023; updates and follow up from the SAMHSA NAC meeting of April 27, 2023; recap of the joint meetings of the councils (JNAC) and Lessons Learned; presentations and council discussions on the following topics: Kids Online Health and Safety; Technical Assistance and Training Strategy, and Strategic Plan Updates; and a general council discussion and public comments.

DATES: August 31, 2023, 10 a.m. to 4 p.m. EDT, Open.

ADDRESSES: 5600 Fishers Lane, Rockville, Maryland 20857 (Pavilion rooms).

FOR FURTHER INFORMATION CONTACT: Carlos Castillo, Committee Management Officer and Designated Federal Official; SAMHSA National Advisory Council, 5600 Fishers Lane, Rockville, Maryland 20857 (mail); telephone: (240) 276–2787; email: *carlos.castillo@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: The SAMHSA NAC was established to advise the Secretary, Department of Health and Human Services (HHS), and the Assistant Secretary for Mental Health and Substance Use, SAMHSA, to improve the provision of treatments and related services to individuals with respect to substance use and to improve prevention services, promote mental health, and protect legal rights of individuals with mental illness and individuals with substance use disorders or misuse.

Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions must be

forwarded to the contact person no later than 7 days before the meeting. Oral presentations from the public will be scheduled for the public comment section at the end of the council discussion. Individuals interested in making oral presentations must notify the contact person by 1 p.m. (EDT), August 24, 2023. Up to three minutes will be allotted for each presentation, and as time permits, as these are presented in the order received. Public comments received will become part of the meeting records.

To obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with the contact person.

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at *https://www.samhsa.gov/about-us/advisory-councils/,* or by contacting Carlos Castillo.

Dated: July 24, 2023.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2023–16088 Filed 7–28–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Joint Meeting of the National Advisory Councils

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given of the combined (joint) meeting on August 30, 2023, of the Substance Abuse and Mental Health Services Administration's (SAMHSA) four National Advisory Councils: the SAMHSA National Advisory Council (NAC), the Center for Mental Health Services NAC, the Center for Substance Abuse Prevention NAC, the Center for Substance Abuse Treatment NAC; and the two SAMHSA Advisory Committees: Advisory Committee for Women's Services (ACWS) and the Tribal Technical Advisory Committee (TTAC).

SUPPLEMENTARY INFORMATION: The meeting will include remarks from the Assistant Secretary for Mental Health and Substance Use; an *In Memoriam* of a TTAC member; follow up discussion from the JNAC meeting of April 26, 2023 by the Assistant Secretary for Mental Health and Substance Use; updates and discussion of the individual meetings for the ACWS, TTAC, CSAT NAC, CSAP NAC, and CMHS NAC of August 29, 2023; presentations and discussions on Integration, Long COVID; Equity, LGBTQI+; and Recovery Support, followed by general council discussion and Public comments.

The meeting is open to the public and will be held at the North Bethesda Marriott Hotel and Conference Center, 5701 Marinelli Rd, Rockville, MD 20852.

Attendance by the public will be limited to space available. Interested persons may present data, information, or views orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person by August 21, 2023. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations must notify the contact by August 21, 2023. Up to three minutes will be allotted for each presentation, as time permits.

The meeting may be accessed via telephone and remotely via Zoom platform and callers must register. To attend on site, obtain the call-in number, access code, and/or web access link; submit written or brief oral comments; or request special accommodations for persons with disabilities, please register on-line at: *https://snacregister.samhsa.gov,* or communicate with SAMHSA's Committee Management Officer, Carlos Castillo (see contact information below).

Meeting information and a roster of Council members may be obtained either by accessing the SAMHSA Council's website at: *https://www.samhsa.gov/about-us/advisory-councils,* or by contacting Carlos Castillo. Substantive program information may be obtained after the meeting by accessing the SAMHSA Council's website at: *https://www.samhsa.gov/about-us/advisory-councils.*

Council Names:

Substance Abuse and Mental Health Services Administration National Advisory Council
Center for Mental Health Services National Advisory Council
Center for Substance Abuse Prevention National Advisory Council
Center for Substance Abuse Treatment National Advisory Council
Advisory Committee for Women's Services
Tribal Technical Advisory Committee

Date/Time/Type: August 30, 2023, 9:00 a.m. to 4:30 p.m. EDT, Open.

Place: North Bethesda Marriott Hotel and Conference Center, 5701 Marinelli Rd, Rockville, MD 20852.

Contact: Carlos Castillo, Committee Management Officer, Room 18EO5C, 5600 Fishers Lane, Rockville, Maryland 20857 (mail), Telephone: (240) 276–2787, Email: *carlos.castillo@samhsa.hhs.gov.*

SAMHSA's National Advisory Councils were established to advise the Secretary, Department of Health and Human Services (HHS); the Assistant Secretary for Mental Health and Substance Use, SAMHSA; and SAMHSA's Center Directors concerning matters relating to the activities carried out by and through the Centers and the policies respecting such activities.

Under section 501 of the Public Health Service Act, the ACWS is statutorily mandated to advise the SAMHSA Assistant Secretary for Mental Health and Substance Use and the Associate Administrator for Women's Services on appropriate activities to be undertaken by SAMHSA and its Centers with respect to women's substance abuse and mental health services.

Pursuant to Presidential Executive Order No. 13175, November 6, 2000, and the Presidential Memorandum of September 23, 2004, SAMHSA established the TTAC for working with federally recognized Tribes to enhance the government-to-government relationship, and honor Federal trust responsibilities and obligations to Tribes and American Indian and Alaska Natives. The SAMHSA TTAC serves as an advisory body to SAMHSA.

Dated: July 23, 2023.

Carlos Castillo,

Committee Management Officer.

[FR Doc. 2023–16087 Filed 7–28–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0031]

Foreign Assembler's Declaration

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border

Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than August 30, 2023) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (88 FR 13455) on March 03, 2023, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Foreign Assembler's Declaration.

OMB Number: 1651–0031.

Form Number: N/A.

Current Actions: Extension without change.

Type of Review: Extension (without change).

Affected Public: Businesses.

Abstract: In accordance with 19 CFR 10.24, a Foreign Assembler's Declaration must be made in connection with the entry of assembled articles under subheading 9802.00.80, Harmonized Tariff Schedule of the United States (HTSUS, 19 U.S.C. 1202). This declaration includes information such as the quantity, value and description of the imported merchandise. The declaration is made by the person who performed the assembly operations abroad and it includes an endorsement by the importer. The Foreign Assembler's Declaration is used by CBP to determine whether the operations performed are within the purview of subheading 9802.00.80, HTSUS and therefore eligible for preferential tariff treatment.

19 CFR 10.24(c) and (d) require that the importer/assembler maintain records for 5 years from the date of the related entry and that they make these records readily available to CBP for audit, inspection, copying, and reproduction.

Instructions for complying with this regulation are posted on the *CBP.gov* website at: *http://www.cbp.gov/trade/trade-community/outreach-programs/trade-agreements/nafta/repairs-alterations/subchpt-9802.*

This collection of information applies to the importing and trade community who are familiar with import procedures and with the CBP regulations.

Type of Information Collection: Foreign Assembler's Declaration (Reporting).

Estimated Number of Respondents: 2,730.

Estimated Number of Annual Responses per Respondent: 128.

Estimated Number of Total Annual Responses: 349,440.

Estimated Time per Response: 50 minutes.

Estimated Total Annual Burden Hours: 291,083.

Type of Information Collection: Foreign Assembler's Declaration (Record Keeping).

Estimated Number of Respondents: 2,730.

Estimated Number of Annual Responses per Respondent: 128.

Estimated Number of Total Annual Responses: 349,440.

Estimated Time per Response: 5 minutes.

Estimated Total Annual Burden Hours: 29,004.

Dated: July 26, 2023.

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2023–16157 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0002]

General Declaration (CBP Form 7507)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; revision of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than August 30, 2023) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting

''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (88 FR 13455) on March 03, 2023, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: General Declaration.

OMB Number: 1651–0002.

Form Number: CBP Form 7507.

Current Actions: CBP proposes to reduce the burden for this information collection by streamlining the Form 7507 and removing certain data elements.

Type of Review: Revision.

Affected Public: Businesses.

Abstract: CBP Form 7507, *General Declaration,* must be filed for all aircraft required to enter or depart under the provisions of 19 CFR 122.41 or 122.61. This form is used to document entrance and clearance for arriving and departing aircraft at the required inspection facilities and inspections by appropriate regulatory agency staffs. Flight identifying information, including the aircraft registration number, which is not collected elsewhere by CBP, and a declaration attesting to the accuracy, completeness and truthfulness of all other documents that make up the manifest shall be submitted on the CBP Form 7507 for aircraft entering or departing the United States, with certain exceptions.

New Change:

To reduce paperwork and reduce duplication of information, the CBP Form 7507 is being streamlined, and will no longer require respondents to provide passenger and crew information, a declaration of health for the persons on board, and details about disinfecting and sanitizing treatments during the flight. The *General Declaration* (CBP Form 7507) will now only contain:

1. Flight identifying information.

2. The aircraft registration number (if not otherwise collected or received by CBP).

3. A declaration attesting to the accuracy, completeness, and truthfulness of all other documents that make up the manifest.

CBP Form 7507 is authorized by 19 U.S.C. 1431, 1433, and 1644a; and provided for by 19 CFR 122.43, 122.52, 122.54, 122.73, and 122.144. This form is accessible at *https://www.cbp.gov/newsroom/publications/forms.*

Type of Information Collection: CBP Form 7507.

Estimated Number of Respondents: 500.

Estimated Number of Annual Responses per Respondent: 2,644.

Estimated Number of Total Annual Responses: 1,322,000.

Estimated Time per Response: 2 minutes.

Estimated Total Annual Burden Hours: 44,023.

Dated: July 26, 2023.

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2023–16154 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0106]

Application To Pay Off or Discharge Alien Crewman (Form I–408)

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than August 30, 2023) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (88 FR 13454) on March 3, 2023, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Application to Pay Off or Discharge Alien Crewman.

OMB Number: 1651–0106.

Form Number: Form I–408.

Current Actions: CBP is proposing to extend this information collection with a increase in burden due to an increase in the number of respondents and responses received.[1]

Type of Review: Extension (with change).

Affected Public: Businesses.

Abstract: CBP Form I–408, Application to Pay Off or Discharge Alien Crewman, is used as an application to request authorization from the Secretary of Homeland Security to pay off or discharge an alien crewman by the owner, agent, consignee, charterer, master, or commanding officer of the vessel or aircraft on which the alien crewman arrived in the United States. This form is submitted to the CBP officer having jurisdiction over the area in which the vessel or aircraft is located at the time of application. CBP Form I–408 is authorized by section 256 of the Immigration and Nationality Act (8 U.S.C. 1286) and provided for by 8 CFR 252.1(h). This form is accessible at: *https://www.cbp.gov/newsroom/publications/forms?title_1=408.*

Type of Information Collection: Form I–408.

Estimated Number of Respondents: 112,500.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 112,500.

Estimated Time per Response: 25 minutes.

Estimated Total Annual Burden Hours: 46,875.

Dated: July 26, 2023.

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2023–16156 Filed 7–28–23; 8:45 am]

BILLING CODE P

[1] CBP inadvertently described this change as a decrease in the 60-Day Notice. 88 FR at 13454; *see also* OMB, Notice of OMB Action (July 23, 2020), *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202003-1651-002#,* (providing the number of responses and burden hours for the currently approved collection).

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651–0063]

Petroleum Refineries in Foreign Trade Sub-Zones

AGENCY: U.S. Customs and Border Protection (CBP), Department of Homeland Security.

ACTION: 30-Day notice and request for comments; extension of an existing collection of information.

SUMMARY: The Department of Homeland Security, U.S. Customs and Border Protection will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). The information collection is published in the **Federal Register** to obtain comments from the public and affected agencies.

DATES: Comments are encouraged and must be submitted (no later than August 30, 2023) to be assured of consideration.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain* . Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional PRA information should be directed to Seth Renkema, Chief, Economic Impact Analysis Branch, U.S. Customs and Border Protection, Office of Trade, Regulations and Rulings, 90 K Street NE, 10th Floor, Washington, DC 20229–1177, Telephone number 202–325–0056 or via email *CBP_PRA@cbp.dhs.gov.* Please note that the contact information provided here is solely for questions regarding this notice. Individuals seeking information about other CBP programs should contact the CBP National Customer Service Center at 877–227–5511, (TTY) 1–800–877–8339, or CBP website at *https://www.cbp.gov/.*

SUPPLEMENTARY INFORMATION: CBP invites the general public and other Federal agencies to comment on the proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). This proposed information collection was previously published in the **Federal Register** (88 FR 12971) on March 01, 2023, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.8. Written comments and suggestions from the public and affected agencies should address one or more of the following four points: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) suggestions to enhance the quality, utility, and clarity of the information to be collected; and (4) suggestions to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The comments that are submitted will be summarized and included in the request

for approval. All comments will become a matter of public record.

Overview of This Information Collection

Title: Petroleum Refineries in Foreign Trade Sub-zones.

OMB Number: 1651–0063.

Form Number: N/A.

Current Actions: Extension with a decrease in burden but no change to the information collected or method of collection.

Type of Review: Extension (with change).

Affected Public: Businesses.

Abstract: The Foreign Trade Zones Act, 19 U.S.C. 81c(d), contains specific provisions for petroleum refinery sub-zones. It permits refiners and U.S. Customs and Border Protection (CBP) to assess the relative value of such multiple products at the end of the manufacturing period during which these products were produced, when the actual quantities of these products resulting from the refining process can be measured with certainty.

19 CFR 146.4(d) provides that the operator of the refinery sub-zone is required to retain all records relating to the above-mentioned activities for five years after the merchandise is removed from the sub-zone. Further, the records shall be readily available for CBP review at the sub-zone.

Instructions on compliance with these record keeping provisions are available in the Foreign Trade Zone Manual which is accessible at: *http://www.cbp.gov/document/guides/foreign-trade-zones-manual.*

Type of Information Collection: Recordkeeping for Petroleum Refineries.

Estimated Number of Respondents: 47.

Estimated Number of Annual Responses per Respondent: 1.

Estimated Number of Total Annual Responses: 47.

Estimated Time per Response: 1,000 hours.

Estimated Total Annual Burden Hours: 47,000.

Dated: July 26, 2023.

Robert F. Altneu,

Director, Regulations and Disclosure Law Division, Regulations and Rulings, Office of Trade, U.S. Customs and Border Protection.

[FR Doc. 2023–16155 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2357]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before October 30, 2023.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2357, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/*

prelimdownload and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Essex County, Massachusetts (All Jurisdictions) **Project: 15–01–0633S Preliminary Date: May 26, 2023**	
City of Beverly	City Hall, 191 Cabot Street, Beverly, MA 01915.
City of Gloucester	City Hall, 9 Dale Avenue, Gloucester, MA 01930.
City of Haverhill	City Hall, 4 Summer Street, Haverhill, MA 01830.
City of Lynn	City Hall, 3 City Hall Square, Lynn, MA 01901.
City of Newburyport	City Hall, 60 Pleasant Street, Newburyport, MA 01950.
City of Peabody	City Hall, 24 Lowell Street, Peabody, MA 01960.
City of Salem	City Hall, 93 Washington Street, Salem, MA 01970.
Town of Andover	Town Hall, 36 Bartlet Street, Andover, MA 01810.
Town of Boxford	Town Hall, 7A Spofford Road, Boxford, MA 01921.
Town of Danvers	Town Hall, 1 Sylvan Street, Danvers, MA 01923.
Town of Essex	Town Hall, 30 Martin Street, Essex, MA 01929.
Town of Georgetown	Town Hall, 1 Library Street, Georgetown, MA 01833.
Town of Groveland	Town Hall, 183 Main Street, Groveland, MA 01834.
Town of Hamilton	Town Hall, 577 Bay Road, Hamilton, MA 01936.
Town of Ipswich	Town Hall, 25 Green Street, Ipswich, MA 01938.
Town of Lynnfield	Town Hall, 55 Summer Street, Lynnfield, MA 01940.
Town of Manchester-by-the-Sea	Town Hall, 10 Central Street, Manchester-by-the-Sea, MA 01944.
Town of Marblehead	Abbot Hall, 188 Washington Street, Marblehead, MA 01945.
Town of Merrimac	Town Hall, 4 School Street, Merrimac, MA 01860.
Town of Middleton	Town Hall, 48 South Main Street, Middleton, MA 01949.
Town of Newbury	Newbury Municipal Offices, 12 Kent Way, Byfield, MA 01922.
Town of North Andover	Town Hall, 120 Main Street, North Andover, MA 01845.
Town of Rockport	Town Hall, 34 Broadway, Rockport, MA 01966.
Town of Rowley	Town Hall, 139 Main Street, Rowley, MA 01969.
Town of Saugus	Town Hall, 298 Central Street, Saugus, MA 01906.
Town of Swampscott	Town Hall, 22 Monument Avenue, Swampscott, MA 01907.
Town of Topsfield	Town Offices, 8 West Common Street, Topsfield, MA 01983.
Town of Wenham	Town Hall, 138 Main Street, Wenham, MA 01984.
Town of West Newbury	Town Hall, 381 Main Street, West Newbury, MA 01985.
Middlesex County, Massachusetts (All Jurisdictions) **Project: 15–01–0633S Preliminary Date: June 08, 2023**	
City of Cambridge	City Hall, 795 Massachusetts Avenue, Cambridge, MA 02139.
City of Everett	City Hall, 484 Broadway, Everett, MA 02149.
City of Lowell	City Hall, 375 Merrimack Street, Lowell, MA 01852.
City of Malden	City Hall, 200 Pleasant Street, Malden, MA 02148.
City of Medford	City Hall, 85 George P. Hassett Drive, Medford, MA 02155.
City of Melrose	City Hall, 562 Main Street, Melrose, MA 02176.
City of Newton	City Hall, 1000 Commonwealth Avenue, Newton, MA 02459.
City of Somerville	City Hall, 93 Highland Avenue, Somerville, MA 02143.
City of Waltham	City Hall, 610 Main Street, Waltham, MA 02452.
City of Woburn	City Hall, 10 Common Street, Woburn, MA 01801.
Town of Arlington	Town Hall, 730 Massachusetts Avenue, Arlington, MA 02476.
Town of Ashby	Town Hall, 895 Main Street, Ashby, MA 01431.
Town of Ashland	Town Hall, 101 Main Street, Ashland, MA 01721.
Town of Ayer	Town Hall, 1 Main Street, Ayer, MA 01432.
Town of Bedford	Town Hall, 10 Mudge Way, Bedford, MA 01730.
Town of Belmont	Town Hall, 455 Concord Avenue, Belmont, MA 02478.
Town of Billerica	Town Hall, 365 Boston Road, Billerica, MA 01821.
Town of Boxborough	Town Hall, 29 Middle Road, Boxborough, MA 01719.
Town of Burlington	Town Hall, 29 Center Street, Burlington, MA 01803.
Town of Chelmsford	Town Hall, 50 Billerica Road, Chelmsford, MA 01824.
Town of Concord	Town House, 22 Monument Square, Concord, MA 01742.
Town of Dracut	Town Hall, 62 Arlington Street, Dracut, MA 01826.
Town of Dunstable	Town Hall, 511 Main Street, Dunstable, MA 01827.
Town of Groton	Town Hall, 173 Main Street, Groton, MA 01450.
Town of Holliston	Town Hall, 703 Washington Street, Holliston, MA 01746.
Town of Hopkinton	Town Hall, 18 Main Street, Hopkinton, MA 01748.
Town of Lexington	Town Offices, 1625 Massachusetts Avenue, Lexington, MA 02420.
Town of Lincoln	Town Hall, 16 Lincoln Road, Lincoln, MA 01773.
Town of Littleton	Town Hall, 37 Shattuck Street, Littleton, MA 01460.

Community	Community map repository address
Town of Natick	Town Hall, 13 East Central Street, Natick, MA 01760.
Town of North Reading	Town Hall, 235 North Street, North Reading, MA 01864.
Town of Pepperell	Town Hall, 1 Main Street, Pepperell, MA 01463.
Town of Reading	Town Hall, 16 Lowell Street, Reading, MA 01867.
Town of Sherborn	Town Hall, 19 Washington Street, Sherborn, MA 01770.
Town of Shirley	Town Hall, 7 Keady Way, Shirley, MA 01464.
Town of Stoneham	Town Hall, 35 Central Street, Stoneham, MA 02180.
Town of Tewksbury	Town Hall, 1009 Main Street, Tewksbury, MA 01876.
Town of Townsend	Town Hall, 272 Main Street, Townsend, MA 01469.
Town of Tyngsborough	Town Hall, 25 Bryants Lane, Tyngsborough, MA 01879.
Town of Wakefield	Town Hall, 1 Lafayette Street, Wakefield, MA 01880.
Town of Watertown	Town Hall, 149 Main Street, Watertown, MA 02472.
Town of Wayland	Town Hall, 41 Cochituate Road, Wayland, MA 01778.
Town of Westford	Town Hall, 55 Main Street, Westford, MA 01886.
Town of Weston	Town Hall, 11 Town House Road, Weston, MA 02493.
Town of Wilmington	Town Hall, 121 Glen Road, Wilmington, MA 01887.
Town of Winchester	Town Hall, 71 Mt. Vernon Street, Winchester, MA 01890.
Norfolk County, Massachusetts (All Jurisdictions) **Project: 15–01–0633S Preliminary Date: April 07, 2023**	
City of Quincy	City Hall, 1305 Hancock Street, Quincy, MA 02169.
Town of Avon	Town Hall, 65 East Main Street, Avon, MA 02322.
Town of Bellingham	Municipal Center, 10 Mechanic Street, Bellingham, MA 02019.
Town of Braintree	Town Hall, 1 John F. Kennedy Memorial Drive, Braintree, MA 02184.
Town of Brookline	Town Hall, 333 Washington Street, Brookline, MA 02445.
Town of Canton	Town Hall, 801 Washington Street, Canton, MA 02021.
Town of Cohasset	Town Hall, 41 Highland Avenue, Cohasset, MA 02025.
Town of Dedham	Town Hall, 450 Washington Street, Dedham, MA 02026.
Town of Dover	Town House, 5 Springdale Avenue, Dover, MA 02030.
Town of Foxborough	Town Hall, 40 South Street, Foxborough, MA 02035.
Town of Franklin	Town Hall, 355 East Central Street, Franklin, MA 02038.
Town of Holbrook	Town Hall, 50 North Franklin Street, Holbrook, MA 02343.
Town of Medfield	Town House, 459 Main Street, Medfield, MA 02052.
Town of Medway	Town Hall, 155 Village Street, Medway, MA 02053.
Town of Millis	Veterans Memorial Building, 900 Main Street, Millis, MA 02054.
Town of Milton	Town Office Building, 525 Canton Avenue, Milton, MA 02186.
Town of Needham	Town Hall, 1471 Highland Avenue, Needham, MA 02492.
Town of Norfolk	Town Hall, 1 Liberty Lane, Norfolk, MA 02056.
Town of Norwood	Town Hall, 566 Washington Street, Norwood, MA 02062.
Town of Plainville	Town Hall, 142 South Street, Plainville, MA 02762.
Town of Randolph	Town Hall, 41 South Main Street, Randolph, MA 02368.
Town of Sharon	Town Office Building, 90 South Main Street, Sharon, MA 02067.
Town of Stoughton	Town Hall, 10 Pearl Street, Stoughton, MA 02072.
Town of Walpole	Town Hall, 135 School Street, Walpole, MA 02081.
Town of Wellesley	Town Hall, 888 Worcester Street, Wellesley, MA 02482.
Town of Westwood	Town Hall, 580 High Street, Westwood, MA 02090.
Town of Weymouth	Town Hall, 75 Middle Street, Weymouth, MA 02189.
Town of Wrentham	Town Hall, 79 South Street, Wrentham, MA 02093.
Worcester County, Massachusetts (All Jurisdictions) **Project: 16–01–0276S Preliminary Date: May 05, 2023**	
City of Fitchburg	City Hall, 718 Main Street, Fitchburg, MA 01420.
City of Gardner	City Hall, 95 Pleasant Street, Gardner, MA 01440.
City of Leominster	City Hall, 25 West Street, Leominster, MA 01453.
City of Worcester	City Hall, 455 Main Street, Worcester, MA 01608.
Town of Ashburnham	Town Hall, 32 Main Street, Ashburnham, MA 01430.
Town of Berlin	Town Offices, 23 Linden Street, Berlin, MA 01503.
Town of Bolton	Town Hall, 663 Main Street, Bolton, MA 01740.
Town of Boylston	Town Hall, 221 Main Street, Boylston, MA 01505.
Town of Clinton	Town Hall, 242 Church Street, Clinton, MA 01510.
Town of Harvard	Town Hall, 13 Ayer Road, Harvard, MA 01451.
Town of Holden	Starbard Building, 1204 Main Street, Holden, MA 01520.
Town of Hopedale	Town Office, 78 Hopedale Street, Hopedale, MA 01747.
Town of Hubbardston	Town Hall, 7 Main Street, Hubbardston, MA 01452.
Town of Lancaster	Prescott Building, 701 Main Street, Lancaster, MA 01523.
Town of Lunenburg	Town Hall, 17 Main Street, Lunenburg, MA 01462.
Town of Mendon	Town Hall, 20 Main Street, Mendon, MA 01756.
Town of Milford	Town Hall, 52 Main Street, Milford, MA 01757.
Town of Paxton	Town Hall, 697 Pleasant Street, Paxton, MA 01612.
Town of Princeton	Town Hall, 6 Town Hall Drive, Princeton, MA 01541.
Town of Rutland	Town Hall, 250 Main Street, Rutland, MA 01543.
Town of Sterling	Butterick Municipal Building, 1 Park Street, Sterling, MA 01564.

Community	Community map repository address
Town of West Boylston	Town Hall, 140 Worcester Street, West Boylston, MA 01583.
Town of Westminster	Town Hall, 11 South Street, Westminster, MA 01473.

[FR Doc. 2023–16142 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities.

DATES: Each LOMR was finalized as in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard information is the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

This new or modified flood hazard information, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Alabama: Limestone (FEMA Docket No.: B–2341).	Unincorporated areas of Limestone County (22–04–5392P).	Collin Daly, Chair, Limestone County Commission, 310 West Washington Street, Athens, AL 35611.	Limestone County Engineering Department, 310 West Washington Street, Athens, AL 35611.	Jul. 21, 2023	010307
Arkansas:					
Sebastian (FEMA Docket No.: B–2324).	City of Fort Smith (22–06–0574P).	Carl Geffken, City of Fort Smith Administrator, 623 Garrison Avenue, Room 315, Fort Smith, AR 72901.	City Hall, 623 Garrison Avenue, Fort Smith, AR 72901.	Jun. 28, 2023	055013
Sebastian (FEMA Docket No.: B–2324).	Unincorporated areas of Sebastian County, (22–06–0574P).	The Honorable Steve Hotz, Sebastian County Judge, 35 South 6th Street, Room 106, Fort Smith, AR 72901.	Sebastian County Courthouse, 35 South 6th Street, Fort Smith, AR 72901.	Jun. 28, 2023	050462
Colorado:					
Arapahoe (FEMA Docket No.: B–2334).	City of Centennial, (21–08–1158P).	The Honorable Stephanie Piko, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 7437 South Fairplay Street, Centennial, CO 80112.	Jul. 7, 2023	080315
Arapahoe (FEMA Docket No.: B–2334).	Unincorporated areas of Arapahoe County, (21–08–1158P).	The Honorable Carrie Warren-Gully, Chair, Arapahoe County Board of Commissioners, 5334 South Prince Street, Littleton, CO 80120.	Arapahoe County Public Works and Development Department, 6924 South Lima Street, Centennial, CO 80112.	Jul. 7, 2023	080011

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Douglas (FEMA Docket No.: B–2334).	Town of Parker, (21–08–1158P).	The Honorable Jeff Toborg, Mayor, Town of Parker, 20120 East Main Street, Parker, CO 80138.	Public Works and Engineering Department, 20120 East Main Street, Parker, CO 80138.	Jul. 7, 2023	080310
Douglas (FEMA Docket No.: B–2334).	Unincorporated areas of Douglas County, (21–08–1158P).	The Honorable Abe Laydon, Chair, Douglas County Board of Commissioners, 100 3rd Street, Castle Rock, CO 80104.	Douglas County Public Works Department, Engineering Division, 100 3rd Street, Castle Rock, CO 80104.	Jul. 7, 2023	080049
Elbert (FEMA Docket No.: B–2324).	Town of Elizabeth, (22–08–0561P).	Patrick Davidson, Town of Elizabeth Administrator, P.O. Box 159, Elizabeth, CO 80107.	Town Hall, 321 South Banner Street, Elizabeth, CO 80107.	Jun. 30, 2023	080056
Elbert (FEMA Docket No.: B–2324).	Unincorporated areas of Elbert County, (22–08–0561P).	The Honorable Chris Richardson, Chair, Elbert County Board of Commissioners, P.O. Box 7, Kiowa, CO 80117.	Elbert County Government Building, 215 Comanche Street, Kiowa, CO 80117.	Jun. 30, 2023	080055
El Paso (FEMA Docket No.: B–2334).	City of Colorado Springs, (22–08–0112P).	The Honorable John Suthers, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Colorado Springs, CO 80903.	City Hall, 30 South Nevada Avenue, Colorado Springs, CO 80903.	Jun. 12, 2023	080060
El Paso (FEMA Docket No.: B–2334).	City of Colorado Springs, (22–08–0120P).	The Honorable John Suthers, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	Jun. 16, 2023	080060
El Paso (FEMA Docket No.: B–2334).	City of Manitou Springs, (22–08–0120P).	The Honorable John Graham, Mayor, City of Manitou Springs, 606 Manitou Avenue, Manitou Springs, CO 80829.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	Jun. 16, 2023	080063
El Paso (FEMA Docket No.: B–2334).	Unincorporated areas of El Paso, (22–08–0112P).	Cami Bremer, Chair, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	Jun. 12, 2023	080059
El Paso (FEMA Docket No.: B–2334).	Unincorporated areas of El Paso, (22–08–0120P).	Cami Bremer, Chair, El Paso County Board of Commissioners, 200 South Cascade Avenue, Suite 100, Colorado Springs, CO 80903.	Pikes Peak Regional Building Department, 2880 International Circle, Colorado Springs, CO 80910.	Jun. 16, 2023	080059
Jefferson (FEMA Docket No.: B–2334).	Unincorporated areas of Jefferson, (22–08–0273P).	Andy Kerr, Chair, Jefferson County Board of Commissioners, 100 Jefferson County Parkway, Suite 5550, Golden, CO 80419.	Jefferson County Planning and Zoning Division, 100 Jefferson County Parkway, Suite 3550, Golden, CO 80419.	Jun. 16, 2023	080087
Florida:					
Charlotte (FEMA Docket No.: B–2324).	City of Punta Gorda, (22–04–4835P).	The Honorable Lynne Matthews, Mayor, City of Punta Gorda, 326 West Marion Avenue, Punta Gorda, FL 33950.	Building Department, 326 West Marion Avenue, Punta Gorda, FL 33950.	Jun. 30, 2023	120062
Charlotte (FEMA Docket No.: B–2334).	Unincorporated areas of Charlotte County, (22–04–5841P).	The Honorable Bill Truex, Chair, Charlotte County Board of Commissioners, 18500 Murdock Circle, Suite 536, Port Charlotte, FL 33948.	Charlotte County Building Department, 18400 Murdock Circle, Port Charlotte, FL 33948.	Jun. 16, 2023	120061
Collier (FEMA Docket No.: B–2335).	City of Naples, (22–04–5499P).	Jay Boodheshwar, Manager, City of Naples, 735 8th Street South, Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	Jun. 12, 2023	125130
Monroe (FEMA Docket No.: B–2334).	Village of Islamorada, (23–04–0523P).	The Honorable Joseph Buddy Pinder III, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	Jun. 15, 2023	120424
Polk (FEMA Docket No.: B–2324).	Unincorporated areas of Polk County, (22–04–2066P).	Bill Beasley, Polk County Manager, 330 West Church Street, Bartow, FL 33831.	Polk County Land Development Division, 330 West Church Street, Bartow, FL 33831.	Jun. 15, 2023	120261
Nevada: Clark (FEMA Docket No.: B–2334).	City of Henderson, (22–09–1748P).	Richard Derrick, Manager, City of Henderson, 240 South Water Street, Henderson, NV 89015.	City Hall, 240 South Water Street, Henderson, NV 89015.	Jul. 21, 2023	320005
Texas:					
Bexar (FEMA Docket No.: B–2334).	City of San Antonio, (22–06–1471P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	Jun. 12, 2023	480045
Bexar (FEMA Docket No.: B–2334).	City of San Antonio, (22–06–1722P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O. Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvements Department, Storm Water Division, 1901 South Alamo Street, 2nd Floor, San Antonio, TX 78204.	Jul. 3, 2023	480045
Bexar (FEMA Docket No.: B–2334).	Unincorporated areas of Bexar County, (22–06–1722P).	The Honorable Peter Sakai, Bexar County Judge, 101 West Nueva Street, 10th Floor, San Antonio, TX 78205.	Bexar County Public Works Department, 1948 Probandt Street, San Antonio, TX 78205.	Jul. 3, 2023	480035
Brazos (FEMA Docket No.: B–2324).	City of Bryan, (22–06–1930P).	The Honorable Bobby Gutierrez, Mayor, City of Bryan, P.O. Box 1000, Bryan, TX 77805.	City Hall, 300 South Texas Avenue, Bryan, TX 77803.	Jun. 28, 2023	480082

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Collin (FEMA Docket No.: B–2324).	Town of Prosper, (22–06–1698P).	The Honorable David F. Bristol, Mayor, Town of Prosper, 250 West 1st Street, Prosper, TX 75078.	Town Hall, 250 West 1st Street, Prosper, TX 75078.	Jun. 22, 2023	480141
Collin (FEMA Docket No.: B–2334).	Unincorporated areas of Collin County, (22–06–2276P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	Jun. 26, 2023	480130
Dallas (FEMA Docket No.: B–2335).	City of Dallas, (22–06–2590P).	The Honorable Eric Johnson, Mayor, City of Dallas, 1500 Marilla Street, Suite 5EN, Dallas, TX 75201.	Oak Cliff Municipal Center, 320 East Jefferson Blvd. Suite 312, Dallas, TX 75203.	Jun. 20, 2023	480171
McLennan (FEMA Docket No.: B–2334).	City of Bellmead, (21–06–2238P).	The Honorable Travis Gibson, Mayor City of Bellmead, 3015 Bellmead Drive, Bellmead, TX 76705.	Department of Public Works, 3015 Bellmead Drive, Bellmead, TX 76705.	Jun. 12, 2023	480457
McLennan (FEMA Docket No.: B–2334).	City of Beverly Hills, (21–06–2238P).	Priscilla Trejo-Serrato, Acting Mayor, City of Beverly Hills, 3418 Memorial Drive, Beverly Hills, TX 76711.	City Hall, 3418 Memorial Drive, Beverly Hills, TX 76711.	Jun. 12, 2023	480925
McLennan (FEMA Docket No.: B–2334).	City of McGregor, (21–06–2238P).	The Honorable James S. Hering, Mayor, City of McGregor, 488 Windsor Road, McGregor, TX 76657.	Community Development Department, 302 South Madison Street, McGregor, TX 76657.	Jun. 12, 2023	480459
McLennan (FEMA Docket No.: B–2334).	City of Waco, (21–06–2238P).	The Honorable Dillon Meek, Mayor, City of Waco, P.O. Box 2570, Waco, TX 76702.	Public Works Department, 401 Franklin Avenue, Waco, TX 76701.	Jun. 12, 2023	480461
McLennan (FEMA Docket No.: B–2334).	Unincorporated areas of McLennan County, (21–06–2238P).	The Honorable Scott M. Felton, McLennan County Judge, 501 Washington Avenue, Suite 214, Waco, TX 76701.	McLennan County Engineering and Mapping Department, 215 North 5th Street, Suite 130, Waco, TX 76701.	Jun. 12, 2023	480456
Tarrant (FEMA Docket No.: B–2324).	City of Fort Worth, (22–06–2438P).	The Honorable Mattie Parker, Mayor, City of Fort Worth, 200 Texas Street, Fort Worth, TX 76102.	Transportation and Public Works Department, Engineering Vault, 200 Texas Street, Fort Worth, TX 76102.	Jun. 29, 2023	480596
Travis (FEMA Docket No.: B–2324).	Unincorporated areas of Travis County, (22–06–2228P).	The Honorable Andy Brown, Travis County Judge, P.O. Box 1748, Austin, TX 78767.	Travis County Floodplain Management Department, 700 Lavaca Street, 5th Floor, Austin, TX 78701.	Jun. 20, 2023	481026

[FR Doc. 2023–16144 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2023–0011; OMB No. 1660–0015]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; Revisions to National Flood Insurance Program Maps: Application Forms and Instructions for (C)LOMAs and (C)LOMR–Fs

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission seeks comments concerning information required by FEMA to amend or revise National Flood Insurance Program (NFIP) maps to remove certain property from the one-percent annual chance floodplain.

DATES: Comments must be submitted on or before August 30, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C Street SW, Washington, DC 20472, email address: *FEMA-Information-Collections-Management@fema.dhs.gov* or Bryan Anderson, FEMA, Federal Insurance & Mitigation Administration, at (202) 577–2397 or *Bryanb.Anderson@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP) is authorized by the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4001 *et seq.* The Federal Emergency Management Agency (FEMA) administers the NFIP and maintains the maps that depict flood hazard information. The land area covered by the floodwaters of the base flood is the Special Flood Hazard Area (SFHA) on NFIP maps. The SFHA is the area where the NFIP's floodplain management regulations must be enforced and the area where the mandatory purchase of flood insurance applies. If a SFHA has been determined to exist for property and the owner or lessee of the property believes his/her property has been incorrectly included in a SFHA, information can be provided to support removal of the SFHA designation. NFIP regulations, at 44 CFR parts 65 and 70, outline the data that must be submitted by an owner or lessee of property who believes their property has been incorrectly included in a SFHA. In order to remove an area from a SFHA, the owner or lessee of the property must submit scientific or technical data demonstrating that the

area is ''reasonably safe from flooding'' and not in the SFHA.

This proposed information collection previously published in the **Federal Register** on April 25, 2023, at 88 FR 25004 with a 60-day public comment period. Two public comments were received, but neither are germane to this collection because the comments did not discuss these instruments or the information they collect. This information collection is set to expire on July 31, 2023. FEMA is requesting a revision to the currently approved information collection. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: Revisions to National Flood Insurance Program Maps: Application Forms and Instructions for (C)LOMAs and (C)LOMR–Fs.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0015.

FEMA Forms: FEMA Form FF–206–FY–23–104 (formerly 086–0–22) and FEMA Form FF–206–FY–23–104–A (formerly 086–0–22A (Spanish)), Application Form for Single Residential Lot or Structure Amendments to National Flood Insurance Program Maps; FEMA Form FF–206–FY–23–105 (formerly 086–0–26), Property Information Form; FEMA Form FF–206–FY–23–106 (formerly 086–0–26A), Elevation Form; and FEMA Form FF–206–FY–23–107 (formerly 086–0–26B), Community Acknowledgment Form.

Abstract: FEMA collects scientific and technical data submissions to determine whether a specific property is located within or outside of a SFHA. If the property is determined not to be within a SFHA, FEMA provides a written determination and the appropriate map is modified by a Letter of Map Amendment (LOMA) or a Letter of Map Revision—Based on Fill (LOMR–F), making it possible for the lending institution to waive the flood insurance requirement.

Affected Public: Individuals or households; Business or other for-profit institutions; State, Local or Tribal government.

Estimated Number of Respondents: 67,701.

Estimated Number of Responses: 67,701.

Estimated Total Annual Burden Hours: 71,234.

Estimated Total Annual Respondent Cost: $3,748,747.

Estimated Respondents' Operation and Maintenance Costs: $12,215,500.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $112,732.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the Agency, including whether the information shall have practical utility; (b) 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2023–16180 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2356]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before October 30, 2023.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2356, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are

used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Logan County, North Dakota and Incorporated Areas **Project: 20–08–0036S Preliminary Date: December 15, 2022**	
City of Napoleon	City Hall, 225 Lake Avenue W, Napoleon, ND 58561.
Unincorporated Areas of Logan County	Logan County Courthouse, 301 Broadway Street, Napoleon, ND 58561.
Wasco County, Oregon and Incorporated Areas **Project: 20–10–0029S Preliminary Date: October 14, 2022**	
City of Dufur	City Hall, 175 Northeast 3rd Street, Dufur, OR 97021.
City of Maupin	City Hall, 507 Grant Avenue, Maupin, OR 97037.
City of Mosier	City Hall, 208 Washington Street, Mosier, OR 97040.
City of The Dalles	City Hall, 313 Court Street, The Dalles, OR 97058.
Confederated Tribes of Warm Springs Reservation	Tribal Headquarters, 1233 Veterans Street, Warm Springs, OR 97761.
Unincorporated Areas of Wasco County	Wasco County Planning Department, 2705 East 2nd Street, The Dalles, OR 97058.

[FR Doc. 2023–16141 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2023–0002; Internal Agency Docket No. FEMA–B–2351]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

DATES: Comments are to be submitted on or before October 30, 2023.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2351, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act

of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. These flood hazard determinations are used to meet the floodplain management requirements of the NFIP.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Nicholas A. Shufro,

Deputy Assistant Administrator for Risk Management, Federal Emergency Management Agency, Department of Homeland Security.

Community	Community map repository address
Kenai Peninsula Borough, Alaska and Incorporated Areas Project: 20–10–0002S Preliminary Date: January 31, 2023	
City of Kenai	City Hall, 210 Fidalgo Avenue, Kenai, AK 99611.
City of Soldotna	City Hall, 117 North Birch Street, Soldotna, AK 99669.
Kenai Peninsula Borough	Kenai Peninsula Borough Administration Building, 144 North Binkley Street, Soldotna, AK 99669.
Lake County, California and Incorporated Areas Project: 18–09–0042S Preliminary Date: October 31, 2022	
Unincorporated Areas of Lake County	Lake County Department of Public Works, 255 North Forbes Street, Room 309, Lakeport, CA 95453.
Madison County, Montana and Incorporated Areas Project: 18–08–0001S Preliminary Date: February 24, 2023	
Town of Ennis	Town Hall, 328 West Main Street, Ennis, MT 59729.
Town of Sheridan	Town Hall, 103 East Hamilton Street, Sheridan, MT 59749.
Town of Twin Bridges	Town Hall, 104 East 6th Avenue, Twin Bridges, MT 59754.
Unincorporated Areas of Madison County	Madison County Commissioners, 103 West Wallace Street, Virginia City, MT 59755.

[FR Doc. 2023–16209 Filed 7–28–23; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0012]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Petition for Alien Relative

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until September 29, 2023.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0012 in the body of the letter, the agency name and Docket ID USCIS–2007–0037. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2007–0037.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a

toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2007–0037 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Alien Relative.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–130; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form I–130 allows U.S. citizens or lawful permanent residents of the United States to petition on behalf of certain alien relatives who wish to immigrate to the United States. Form I–130A allows for the collection of additional information for spouses of the petitioners necessary to facilitate a decision.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–130 is 437,500 and the estimated hour burden per response is 2 hours; the estimated total number of respondents for the information collection I–130A is 40,775 and the estimated hour burden per response is 0.833 hours; the estimated total number of respondents for the information collection I–130 E-filing is 437,500 and the estimated hour burden per response is 1.5 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 1,565,216 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $350,000,000.

Dated: July 21, 2023.

Samantha L. Deshommes,

Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2023–16119 Filed 7–28–23; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6420–N–01]

Preview of The Pathways To Removing Obstacles to Housing (Pro Housing); Funding Opportunity

AGENCY: Office of Community Planning and Development, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice of funding opportunity.

SUMMARY: Through this notice, HUD is announcing the publication of a preview of the Pathways to Removing Obstacles to Housing (PRO Housing) Notice of Funding Opportunity (NOFO) in advance of publication on *Grants.gov*. HUD is making this preview available to allow interested applicants to review the preview of the NOFO, submit questions, and prepare applications. HUD intends to publish the NOFO and allow submission of applications in September of 2023.

FOR FURTHER INFORMATION CONTACT: Jessie Handforth Kome, Director, Office of Block Grant Assistance, Office of Community Planning and Development, Department of Housing and Urban Development, 451 7th Street SW, Room 7282, Washington, DC 20410, telephone number 202–708–3587 x5539. Facsimile inquiries may be sent to Ms. Jessie Handforth Kome at 202–708–0033. These telephone numbers are not toll-free. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: HUD is publishing a preview of the PRO Housing NOFO to give interested applicants time to prepare their applications prior to the opening of the application period. HUD expects that this preview will be available for at least 30 days before HUD publishes the official NOFO on *Grants.gov* and begins to take applications. During this preview, the PRO Housing NOFO preview is available on HUD's website at the following URL: *https://www.hud.gov/grants.*

This NOFO preview is subject to change. While HUD does not intend to make substantive changes at this point, applicants should consider the NOFO published on *Grants.gov* to be the official version.

HUD will not accept applications during the preview period. However,

during this preview, interested applicants may submit questions on the NOFO preview to the following email address: *CDBG-PROHousing@hud.gov* (see Section VII of the NOFO preview). Interested applicants may also conduct the required registration activities for the System for Award Management (SAM), Unique Entity Identifier (UEI), and *Grants.gov* (see Section IV.C. of the NOFO preview).

HUD strongly encourages interested applicants to begin working on their application during the preview period as the NOFO requires public participation (see Section VI.E.5.a.iii of the NOFO preview). Please note that while interested applicants may work on their applications and accompanying materials during the preview period, the NOFO requires that no materials to be submitted be signed before the date the NOFO is published on *Grants.gov*.

HUD anticipates that the PRO Housing NOFO will be published on *Grants.gov* in September 2023. The publication of the PRO Housing NOFO on *Grants.gov* will signal the opening of the application period. The application period will be open for at least 30 days, with applications due October 30, 2023. Applications must be submitted through *Grants.gov*.

HUD will not accept requests for a waiver of electronic submission requirements during the preview period. Such requests may only be submitted once the NOFO has been published on *Grants.gov* (see Section IV.A. of the NOFO preview).

Jessie Kome,

Director, Office of Block Grant Assistance.

[FR Doc. 2023–16266 Filed 7–27–23; 11:15 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNM930000.L14400000.BJ0000.BX0000]

Notice of Filing of Plats of Survey; New Mexico; Oklahoma

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of official filing.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed 30 days after the date of this publication in the Bureau of Land Management (BLM), New Mexico State Office, Santa Fe, New Mexico. The surveys announced in this notice are necessary for the management of lands administered by the agency indicated.

ADDRESSES: This plat will be available for inspection in the New Mexico State Office, Bureau of Land Management, 301 Dinosaur Trail, Santa Fe, New Mexico 85004–4427. Protests of a survey should be sent to the New Mexico State Director at the above address.

FOR FURTHER INFORMATION CONTACT: Michael J. Purtee, Chief Cadastral Surveyor; (505) 761–8903; *mpurtee@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION:

New Mexico Principal Meridian, New Mexico

The plat representing the dependent resurvey and survey of tracts of land in Townships 11 South, Ranges 8 and 9 West, accepted July 26, 2023, for Group No. 1181, New Mexico.

This plat was prepared at the request of the U.S. Department of Agriculture, Gila National Forest, Region 3.

Indian Meridian, Oklahoma

The plat representing the dependent resurvey of a tract of land in Townships 28 North, Ranges 23 and 24 East, accepted May 31, 2023, for Group No. 232, Oklahoma.

This plat was prepared at the request of the Bureau of Indian Affairs, Eastern Oklahoma Regional Office.

A person or party who wishes to protest against this survey must file a written notice of protest within 30 calendar days from the date of this publication with the New Mexico State Director, Bureau of Land Management, stating that they wish to protest.

A statement of reasons for a protest may be filed with the notice of protest to the State Director, or the statement of reasons must be filed with the State Director within 30 days after the protest is filed. Before including your address, or other personal information in your protest, please be aware that your entire protest, including your personal identifying information, may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 43 U.S.C. ch. 3.

Michael J. Purtee,

Chief Cadastral Surveyor of New Mexico.

[FR Doc. 2023–16205 Filed 7–28–23; 8:45 am]

BILLING CODE 4310–FB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SERO–NCPTT–36122; PPWOCRADTI, PCU00PT14.GT0000]

Preservation Technology and Training Board Notice of Public Meeting

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the National Park Service (NPS) is hereby giving notice that the Preservation Technology and Training Board (Board) of the National Center for Preservation Technology and Training (NCPTT) will meet as indicated below.

DATES: The in-person meeting will take place from 9:00 a.m. to 5:00 p.m. (CDT) or until business in completed on Wednesday, August 16, 2023, and from 9:00 a.m. to 12:00 p.m. (CDT) on Thursday, August 17, 2023.

ADDRESSES: The Board will meet at the NCPTT Headquarters, 645 University Parkway, Natchitoches, LA 71457.

FOR FURTHER INFORMATION CONTACT: Anyone interested in attending should contact Kirk A. Cordell, Executive Director, National Center for Preservation Technology and Training, 645 University Parkway, Natchitoches, LA 71457, by telephone (318) 356–7444, or by email *kirk_cordell@nps.gov.* Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Board was established by Congress to provide leadership, policy advice, and professional oversight to the NCPTT in compliance with section 404 of the National Historic Preservation Act of 1966, as amended (54 U.S.C. 305303). All meetings are open to the public and will have time allocated for public testimony.

Purpose of the Meeting: The Board meeting will consist of the following proposed agenda items:

1. Review and Comment on NCPTT FY 2022 Accomplishments, and Operational Priorities for FY 2023
2. FY 2023 and FY 2024 NCPTT Budget and Initiatives
3. Recent Research
4. Training Programs
5. Public Comments
6. Adjournment

The final agenda will be posted on the Board's website at *https://www.nps.gov/subjects/ncptt/ptt-board.htm.* Interested persons may present, either orally or through written comments, information for the Board to consider during the public meeting. Written comments will be accepted prior to, during, or after the meeting. Members of the public may submit written comments by mailing them to the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Due to time constraints during the meeting, the Board is not able to read written public comments submitted into the record. Individuals or groups requesting to make oral comments at the public Board meeting will be limited to no more than three minutes per speaker. All comments will be made part of the public record and will be electronically distributed to all Board members. Detailed minutes of the meeting will be available for public inspection within 90 days of the meeting.

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your written comments, you should be aware that your entire comment including your personal identifying information will be publicly available. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2023–16186 Filed 7–28–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#–36239; PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before July 15, 2023, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted electronically by August 15, 2023.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State≤.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 7228, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 7228, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 15, 2023. Pursuant to section 60.13 of 36 CFR part 60, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers

Key: State, County, Property Name, Multiple Name (if applicable), Address/Boundary, City, Vicinity, Reference Number.

COLORADO

Eagle County

Glassier Farmstead, 0543 Hooks Spur Ln., Basalt vicinity, SG100009260

GEORGIA

Chatham County

Magnolia Park Historic District, Roughly bounded by DeRenne Ave., Latimer and Brogdon Sts., Lovett and Bacon Park Drs., Broadmoor Cir., and Truman Pkwy. Savannah, SG100009267

ILLINOIS

Cook County

Avalon Park Bungalow Historic District, (Chicago Bungalows MPS (Additional Documentation)), Roughly bounded by: East 79th St., South Harper Ave., East 83rd St., and South, Woodlawn Ave., Chicago, MP100009251

Benda House, 211 Southcote Rd., Riverside, SG100009252

Mid-City Trust and Savings Bank, 801 West Madison St., Chicago, SG100009254

Du Page County,

House of Seven Gables, 141 Loretto Ct., Wheaton, SG100009249

Madison County

Collinsville Township High School, 1203 Vandalia St., Collinsville, SG100009253

LOUISIANA

Acadia Parish

Crowley Historic District (Boundary Increase), Roughly bounded by West 7th St., the rear property lines in the 600 blk. of North Parkerson Ave., West 6th St., North Avenue F, and North Avenue G, Crowley, BC100009258

VIRGINIA

Amherst County

Dameron Cottage, 462 South Main St., Amherst, SG100009241

Augusta County

Black Oak Spring, 1709 Dam Town Rd., Fort Defiance vicinity, SG100009242

Russell County

Dante Downtown Historic District, Bunch Town, Straight Hollow, and Lower Bearwallow Rds., Dante, SG100009243

Shenandoah County

Shenvalee Golf Resort, 9660 Fairway Dr., New Market, SG100009244

Smyth County

Southwestern State Hospital Tubercular Building, 281 Bagley Cir., Marion, SG100009245

A request for removal has been made for the following resources:

UTAH

Box Elder County

Box Elder Flouring Mill (Brigham City MPS), 327 East 200 North, Brigham City, OT89000452

Iron County

ood, George H., House, 432 North Main St., Cedar City, OT78002662

Salt Lake County

Pantages Theatre, 144 South Main St., Salt Lake City, OT100007291

Shubrick Hotel (Salt Lake City Business District MRA), 68 West Four Hundred South, Salt Lake City, OT82005107

Sevier County

Salina Hospital, 330 West Main St., Salina, OT80003966

Utah County

Bunnell, Stephen and Mary, House 970 South 800 West, Utah Valley State College, Orem, OT96001171

Additional documentation has been received for the following resources:

LOUISIANA

Acadia Parish

Crowley Historic District (Additional Documentation), LA 13 and US 90, Crowley, AD82002751

NORTH CAROLINA

Onslow County

Swansboro Historic District (Additional Documentation) (Onslow County MPS) Roughly bounded by Walnut, Main, and Elm Sts., NC 24, White Oak River, and Church, Water, and Broad Sts., Swansboro, AD90000440

Authority: Section 60.13 of 36 CFR part 60.

Dated: July 19, 2023.

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2023–16106 Filed 7–28–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–AKRO–ANIA–DENA–CAKR–LACL–KOVA–WRST–GAAR–36111; PPAKAKROR4; PPMPRLE1Y.LS0000]

Public Meetings of the National Park Service Alaska Region Subsistence Resource Commission Program

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: The National Park Service (NPS) is hereby giving notice that the Aniakchak National Monument Subsistence Resource Commission (SRC), the Denali National Park SRC, the Cape Krusenstern National Monument SRC, the Lake Clark National Park SRC, the Kobuk Valley National Park SRC, the Wrangell-St. Elias National Park SRC, and the Gates of the Arctic National Park SRC will meet as indicated below.

DATES: The Aniakchak National Monument SRC will meet in-person and via videoconference from 1:00 p.m. to 5:00 p.m. or until business is completed on Thursday, October 19, 2023. The alternate meeting date is Monday, October 23, 2023, from 1:00 p.m. to 5:00 p.m. or until business is completed at the same location and via videoconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by videoconference.

The Denali National Park SRC will meet in-person and via teleconference from 10:00 a.m. to 5:00 p.m. or until business is completed on Wednesday, August 23, 2023. The alternate meeting date is Wednesday, August 30, 2023, from 10:00 a.m. to 5:00 p.m. or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

The Cape Krusenstern National Monument SRC will meet in-person and via teleconference from 1:00 p.m. to 5:00 p.m. on Wednesday, November 1, 2023, and from 9:00 a.m. to 12:00 p.m. on Thursday, November 2, 2023, or until business is completed. If business is completed on November 1, 2023, the meeting will adjourn, and no meeting will take place on November 2, 2023. The alternate meeting dates are Wednesday, November 8, 2023, from 1:00 p.m. to 5:00 p.m., and Thursday, November 9, 2023, from 9:00 a.m. to 12:00 p.m. or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

The Lake Clark National Park SRC will meet in-person and via teleconference, from 1:00 p.m. to 4:00 p.m. or until business is completed on Wednesday, September 27, 2023. The alternate meeting date is Wednesday, October 18, 2023, from 1:00 p.m. to 4:00 p.m. or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

The Kobuk Valley National Park SRC will meet in-person and via teleconference from 1:00 p.m. to 5:00 p.m. on Monday, October 30, 2023, and from 9:00 a.m. to 12:00 p.m. on Tuesday, October 31, 2023, or until business is completed. If business is completed on October 30, 2023, the meeting will adjourn, and no meeting will take place on October 31, 2023. The alternate meeting dates are Monday, November 6, 2023, from 1:00 p.m. to 5:00 p.m., and Tuesday, November 7, 2023, from 9:00 a.m. to 12:00 p.m. or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

The Wrangell-St. Elias National Park SRC will meet in-person and via teleconference from 9:00 a.m. to 5:00 p.m. or until business is completed on both Wednesday, September 27, 2023, and Thursday, September 28, 2023. If business is completed on September 27, 2023, the meeting will adjourn, and no meeting will take place on September 28, 2023. The alternate meeting dates are Wednesday, October 11, 2023, and Thursday, October 12, 2023, from 9:00 a.m. to 5:00 p.m., or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

The Gates of the Arctic National Park SRC will meet in-person and via teleconference from 9:00 a.m. to 5:00 p.m. or until business is completed on both Tuesday, November 14, 2023, and Wednesday, November 15, 2023. The alternate meeting dates are Thursday, November 16, 2023, from 9:00 a.m. to 5:00 p.m., and Friday, November 17, 2023, from 9:00 a.m. to 5:00 p.m. or until business is completed at the same location and via teleconference. If an in-person meeting is not feasible or advisable, the meeting will be held solely by teleconference.

ADDRESSES: The Aniakchak National Monument SRC will meet in-person at the Port Heiden Community Building, 2200 James Street, Port Heiden AK 99549 and via teleconference. Teleconference participants must call the NPS office at (907) 246–2121 prior to the meeting to receive teleconference passcode information. For more detailed information regarding these meetings, or if you are interested in applying for SRC membership, contact Designated Federal Officer Mark Sturm, Superintendent, at (907) 246–2120 or via email at *mark_sturm@nps.gov,* or Troy Hamon, Subsistence Coordinator, at (907) 246–2121 or via email at *troy_hamon@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Denali National Park SRC will meet in the Community Hall, Cantwell Community Center, Milepost 1 Denali Highway, Cantwell, AK 99729 and via teleconference. Teleconference participants must call the NPS office at (907) 644–3604 prior to the meeting to receive teleconference passcode information. For more detailed

information regarding these meetings, or if you are interested in applying for SRC membership, contact Designated Federal Officer Brooke Merrell, Superintendent, at (907) 683–9627 or via email at *brooke_merrell@nps.gov,* or Amy Craver, Subsistence Coordinator, at (907) 644–3604 or via email at *amy_craver@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Cape Krusenstern National Monument SRC will meet in-person at the Northwest Arctic Heritage Center, 171 3rd Avenue, Kotzebue, AK 99752 and via teleconference. Teleconference participants must call the NPS office at (907) 442–8342 prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Designated Federal Officer Ray McPadden, Superintendent, at (907) 442–3890 or via email at *raymond_mcpadden@nps.gov,* or Emily Creek, Subsistence Coordinator, at (907) 442–8342 or via email at *emily_creek@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Lake Clark National Park SRC will meet in-person at the Nondalton Community Center, 109 Main Street, Nondalton, AK 99640 and via teleconference. Teleconference participants must call the NPS office at (907) 644–3648 prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Designated Federal Officer Susanne Green, Superintendent, at (907) 644–3627 or via email at *susanne_green@nps.gov,* or Liza Rupp, Subsistence Manager, at (907) 644–3648 or via email at *elizabeth_rupp@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Kobuk Valley National Park SRC will meet in-person at the Northwest Arctic Heritage Center, 171 3rd Avenue, Kotzebue, AK 99752 and via teleconference. Teleconference participants must call the NPS office at (907) 442–8342 prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Designated Federal Officer Ray McPadden, Superintendent, at (907) 442–3890 or via email at *raymond_mcpadden@nps.gov,* or Emily Creek, Subsistence Coordinator, at (907) 442–8342 or via email at *emily_creek@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Wrangell-St. Elias National Park SRC will meet in-person at the Copper Center Visitor Center Complex, Wrangell-St. Elias National Park and Preserve, Mile 106.8 Richardson Highway, Copper Center, AK 99573 and via teleconference. Teleconference participants must contact Subsistence Coordinator, Barbara Cellarius, at (907) 822–7236 or *wrst_subsistence@nps.gov* prior to the meeting to receive teleconference passcode information. For more detailed information regarding these meetings, or if you are interested in applying for SRC membership, contact Designated Federal Officer Ben Bobowski, Superintendent, at (907) 822–5234 or via email at *ben_bobowski@nps.gov,* or Barbara Cellarius, Subsistence Coordinator, at (907) 822–7236 or via email at *barbara_cellarius@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

The Gates of the Arctic National Park SRC will meet in-person at Sophie Station Hotel, Zach's Boardroom, 1717 University Avenue, Fairbanks, AK 99709 and via teleconference. Teleconference participants must call the NPS office at (907) 455–0639 prior to the meeting to receive teleconference passcode information. For more detailed information regarding this meeting or if you are interested in applying for SRC membership, contact Designated Federal Officer Mark Dowdle, Superintendent, at (907) 455–0614 or via email at *mark_dowdle@nps.gov,* or Marcy Okada, Subsistence Coordinator, at (907) 455–0639 or via email at *marcy_okada@nps.gov,* or Eva Patton, Federal Advisory Committee Group Federal Officer, at (907) 644–3601 or via email at *eva_patton@nps.gov.*

SUPPLEMENTARY INFORMATION: The NPS is holding meetings pursuant to the Federal Advisory Committee Act (5 U.S.C. ch 10). The NPS SRC program is authorized under title VIII, section 808 of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3118). SRC meetings are open to the public and will have time allocated for public testimony. The public is welcome to present written or oral comments to the SRC. SRC meetings will be recorded, and meeting minutes will be available upon request from the Superintendent for public inspection approximately six weeks after the meeting.

Meeting Accessibility/Special Accommodations: Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact the person listed in the (see **FOR FURTHER INFORMATION CONTACT**) section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis. 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.

Purpose of the Meeting: The agenda may change to accommodate SRC business. The proposed meeting agenda for each meeting includes the following:

1. Call to Order—Confirm Quorum
2. Welcome and Introduction
3. Review and Adoption of Agenda
4. Approval of Minutes
5. Superintendent's Welcome and Review of the SRC Purpose
6. SRC Membership Status
7. SRC Chair and Members' Reports
8. Superintendent's Report
9. Old Business
10. New Business
11. Federal Subsistence Board Update
12. Alaska Boards of Fish and Game Update
13. National Park Service Staff Reports
    a. Ranger Reports
    b. Resource Manager's Report
    c. Subsistence Manager's Report
14. Public and Other Agency Comments
15. Work Session
16. Set Tentative Date and Location for Next SRC Meeting
17. Adjourn Meeting

SRC meeting location and date may change based on inclement weather or exceptional circumstances, including public health advisories or mandates. If the meeting date and location are changed, the Superintendent will issue a press release and use local newspapers and/or radio stations to announce the rescheduled meeting.

Public Disclosure of Comments: Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment

to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. ch. 10.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2023–16097 Filed 7–28–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR040U2000, XXXR4081G3, RX.05940913.FY19400]

Public Meeting of the Glen Canyon Dam Adaptive Management Work Group

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the Bureau of Reclamation (Reclamation) is publishing this notice to announce that a Federal Advisory Committee meeting of the Glen Canyon Dam Adaptive Management Work Group (AMWG) will take place. The meeting is open to the public.

DATES: The meeting will be held in-person and virtually on Wednesday, August 16, 2023, from 9:30 a.m. to approximately 4:30 p.m. (PDT); and Thursday, August 17, 2023, from 8:30 a.m. to approximately 3:00 p.m. (PDT).

ADDRESSES: The in-person meeting will be held at Little America, 2515 East Butler Ave, Flagstaff, Arizona, 86004.

The Wednesday, August 16, 2023, meeting can be accessed virtually at *https://rec.webex.com/rec/j.php?MTID=m67fef4d2de6569962b5cf3f6100b20ca;* Meeting Number: 2762 308 0111, Password: Aug16.

The Thursday, August 17, 2023, meeting can be accessed virtually at *https://rec.webex.com/rec/j.php?MTID=m6f53bcacd46b7bc06307d93be43db425;* Meeting Number: 2761 099 6698, Password: Aug17.

FOR FURTHER INFORMATION CONTACT: Mr. William Stewart, Bureau of Reclamation, telephone (385) 622–2179, email at *wsteawart@usbr.gov.* Individuals who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: The Glen Canyon Dam Adaptive Management Program (GCDAMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of 1992. The AMWG makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam, consistent with the Grand Canyon Protection Act. The AMWG meets two to three times a year.

Agenda: The AMWG will meet to receive updates on: (1) current basin hydrology and water year 2024 operations; (2) experiments considered for implementation in 2024; (3) the status of threatened and endangered species; (4) long-term funding considerations. The AMWG will also discuss other administrative and resource issues pertaining to the GCDAMP. To view a copy of the agenda and documents related to the above meeting, please visit Reclamation's website at *https://www.usbr.gov/uc/progact/amp/amwg.html.*

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact Mr. William Stewart (see **FOR FURTHER INFORMATION CONTACT** section of this notice) at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Time will be allowed on both days for any individual or organization wishing to make extemporaneous and/or formal oral comments. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Interested parties should contact Mr. William Stewart (see **FOR FURTHER INFORMATION CONTACT**) for placement on the public speaker list for this meeting. Members of the public may also choose to submit written comments by emailing them to *wstewart@usbr.gov.* Due to time constraints during the meeting, the AMWG is not able to read written public comments. All written comments will be made part of the public record and will be provided to the AMWG members.

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.

Authority: 5 U.S.C. ch. 10.

William Stewart,

Adaptive Management Group Chief, Upper Colorado Basin—Interior Region 7.

[FR Doc. 2023–16117 Filed 7–28–23; 8:45 am]

BILLING CODE 4332–90–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 231S180110; S2D2S SS08011000 SX064A000 23XS501520; OMB Control Number 1029–0114]

Agency Information Collection Activities; Technical Evaluation Surveys

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 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. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0114 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about

this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. 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. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 7, 2023 (88 FR 20907). No comments were received.

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 series of surveys are needed to ensure that technical assistance activities, technology transfer activities and technical forums are useful for those who participate or receive the assistance. Specifically, representatives from State and Tribal regulatory and reclamation authorities are the primary respondents, although representatives of industry, environmental or citizen groups, or the public, may be recipients of the assistance or may participate in these forums. These surveys are the primary means through which OSMRE evaluates its performance in meeting the performance goals outlined in its annual plans developed pursuant to the Government Performance and Results Act.

Title of Collection: Technical Evaluation Surveys.

OMB Control Number: 1029–0114.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State and Tribal employees.

Total Estimated Number of Annual Respondents: 203.

Total Estimated Number of Annual Responses: 203.

Estimated Completion Time per Response: 5 minutes.

Total Estimated Number of Annual Burden Hours: 17.

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

Frequency of Collection: Annually.

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.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2023–16181 Filed 7–28–23; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 231S180110; S2D2S SS08011000 SX064A000 23XS501520; OMB Control Number 1029–0067]

Agency Information Collection Activities; Restrictions on Financial Interests of State Employees

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the Office of Surface Mining Reclamation and Enforcement (OSMRE), are proposing to renew an information collection.

DATES: Interested persons are invited to submit comments on or before August 30, 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. Please provide a copy of your comments to Mark Gehlhar, Office of Surface Mining Reclamation and Enforcement, 1849 C Street NW, Room 4556–MIB, Washington, DC 20240, or by email to *mgehlhar@osmre.gov.* Please reference OMB Control Number 1029–0067 in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Mark Gehlhar by email at *mgehlhar@osmre.gov,* or by telephone at (202) 208–2716. 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. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

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.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on April 6, 2023 (88 FR 20550). No comments were received.

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: Respondents are state employees who supply information on employment and financial interests. The purpose of the collection is to ensure compliance with section 517(g) of the Surface Mining Control and Reclamation Act of 1977, which places an absolute prohibition on employees of regulatory authorities having a direct or indirect financial interest in underground or surface coal mining operations.

Title of Collection: Restriction on financial interests of State employees.

OMB Control Number: 1029–0067.

Form Number: None.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: State employees.

Total Estimated Number of Annual Respondents: 2,196.

Total Estimated Number of Annual Responses: 4,415.

Estimated Completion Time per Response: Varies from 5 to 30 minutes, depending on activity.

Total Estimated Number of Annual Burden Hours: 377.

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

Frequency of Collection: Once and annually.

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.*).

Mark J. Gehlhar,

Information Collection Clearance Officer, Division of Regulatory Support.

[FR Doc. 2023–16183 Filed 7–28–23; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation, and Liability Act

On July 26, 2023, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Puerto Rico in *United States* v. *HP Inc.,* et al. 3:23–cv–1383.

The United States filed a complaint against HP Inc., Lifetime Brands, Inc., Puerto Rico Industrial Development Company, and Wallace Silversmiths de Puerto Rico Ltd. under section 106 of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9606 relating to releases of hazardous substances at Operable Unit 1 of the San German Groundwater Site in San German, Puerto Rico. The proposed consent decree resolves this claim and requires the defendants to design and implement the remedy selected by the United States Environmental Protection Agency for Operable Unit 1 of the San German Groundwater Site. In addition, the defendants agree to pay the United States' future costs for overseeing the response work.

The publication of this notice opens a period for public comment on the consent decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *HP Inc.,* et al, D.J. Ref. No. 90–11–3–12111. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the proposed consent decree may be examined and downloaded at this Justice Department website: *https://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the proposed consent decree upon email request to *pubcomment-ees.enrd@usdoj.gov.*

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–16182 Filed 7–28–23; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On July 25, 2023, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Ohio in the lawsuit entitled *United States* v. *Globe Metallurgical, Inc.,* Civil Action No. 2:23–cv–02368–MHW.

The proposed Consent Decree resolves claims against Globe Metallurgical, Inc. (''Globe'') related to emissions of hazardous air pollutants from its ferroalloy production facility located in Waterford, Ohio. The Complaint filed in this matter seeks injunctive relief and civil penalties pursuant to sections 113(b) and 167 of the Clean Air Act (CAA), 42 U.S.C.

7413(b) and 7477, for violation of (1) the CAA's Prevention of Significant Deterioration of Air Quality (PSD) provisions; (2) the CAA's New Source Performance Standards (NSPS) provisions and the NSPS regulations for ferroalloy production facilities (subpart Z), and (3) the Ohio State Implementation Plan's opacity limits, as incorporated into Globe's Title V permit, and Ohio's Title V permit program. Under the proposed Consent Decree, Globe will pay a $2.6 million civil penalty, construct a new baghouse, restrict sulfur content of process inputs to specified limits, and implement a detailed monitoring regime to address opacity concerns. Additionally, as mitigation for past exceedances, Globe will extend its sulfur content limits and Subpart Z obligations to all furnaces.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Globe Metallurgical, Inc.,* D.J. Ref. No. 90–5–2–1–11643. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $17.25 (25 cents per page reproduction cost) payable to the United States Treasury.

Patricia S. McKenna,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–16190 Filed 7–28–23; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree

In accordance with Departmental Policy, 28 CFR 50.7, notice is hereby given that a proposed Consent Decree in *United States* v. *Robert Yundt Homes, LLC, et al.,* No. 3:23–cv–00073–JMK, was lodged with the United States District Court for the District of Alaska on July 24, 2023.

This proposed Consent Decree concerns a complaint filed by the United States against Defendants Robert Yundt Homes, LLC, and Robert D. Yundt II, pursuant to sections 309(b) and (d) of the Clean Water Act, 33 U.S.C. 1319(b) and (d), to obtain injunctive relief from and impose civil penalties against Defendants for violating the Clean Water Act by discharging pollutants without a permit into waters of the United States and violating Administrative Orders on Consent issued by the United States Environmental Protection Agency (EPA). The proposed Consent Decree resolves these allegations by requiring Defendants to restore the impacted areas, perform mitigation pursuant to EPA-approved restoration plans, and pay a civil penalty.

The Department of Justice will accept written comments relating to this proposed Consent Decree for 30 days from the date of publication of this Notice. Please address comments to Daniel J. Martin, United States Department of Justice, Environment and Natural Resources Division, Environmental Defense Section, Post Office Box 7611, Washington, DC 20044, or *pubcomment_eds.enrd@usdoj.gov,* and refer to *United States* v. *Robert Yundt Homes, LLC, et al.,* DJ # 90–5–1–1–22275.

The proposed Consent Decree may be examined at the Clerk's Office, United States District Court for the District of Alaska, James M. Fitzgerald United States Courthouse and Federal Building, 222 West 7th Avenue, Room 229, Anchorage, AK 99513. In addition, the proposed Consent Decree may be examined electronically at *http://www.justice.gov/enrd/consent-decrees.*

Cherie Rogers,

Assistant Section Chief, Environmental Defense Section, Environment and Natural Resources Division.

[FR Doc. 2023–16084 Filed 7–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act and Emergency Planning and Community Right-To-Know Act

On July 26, 2023 the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Rhode Island in the lawsuit entitled *United States* v. *Taylor Farms New England, Inc.,* Civil Action No. 1:23–cv–00311.

The United States filed this lawsuit under the Clean Air Act and the Emergency Planning and Community Right-To-Know Act. The United States' complaint seeks injunctive relief and civil penalties for violations of the statutory and regulatory provisions that govern the prevention and notice of accidental releases of extremely hazardous substances at the defendant's food processing facility in North Kingstown, Rhode Island. The consent decree requires the defendant to perform injunctive relief and pay a $650,000 civil penalty.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Taylor Farms New England, Inc.,* D.J. Ref. No. 90–5–2–1–12458. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department website: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—

ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Henry S. Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2023–16191 Filed 7–28–23; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employee Benefits Security Administration

[Prohibited Transaction Exemption 2023–17; Exemption Application No. D–11963]

Exemption From Certain Prohibited Transaction Restrictions Involving J.P. Morgan Securities LLC, J.P. Morgan Investment Management Inc., J.P. Morgan Advisors (Formerly, J.P. Morgan Securities; JPMS Brokerage), and Chase Wealth Management Located in New York, New York

AGENCY: Employee Benefits Security Administration, Labor.

ACTION: Notice of exemption.

SUMMARY: This document contains a notice of exemption issued by the Department of Labor (the Department) from certain of the prohibited transaction restrictions of the Internal Revenue Code of 1986 (the Code). This exemption involves certain principal trades involving J.P. Morgan Securities LLC (JPMS), J.P. Morgan Investment Management Inc. (JPMIM), J.P. Morgan Advisors (formerly, J.P. Morgan Securities; JPMS Brokerage), and Chase Wealth Management (CWM) (collectively, the Applicants), and certain of their client plans that are subject to Code section 4975 but not covered by Title I of ERISA (the Non-ERISA Plan Clients).[1] These principal transactions resulted in the Non-ERISA Plan Clients purchasing or selling securities from or to the Applicants.

DATES: The exemption will be in effect from December 14, 2010, until September 16, 2013.

FOR FURTHER INFORMATION CONTACT: Ms. Anna Vaughan of the Department, telephone (202) 693–8565. (This is not a toll-free number.)

SUPPLEMENTARY INFORMATION: The Applicants requested an individual exemption pursuant to Code section 4975(c)(2) in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011). Effective December 31, 1978, section 102 of the Reorganization Plan No. 4 of 1978, (5 U.S.C. App. 1 (1996)) transferred the authority of the Secretary of the Treasury to issue exemptions of the type requested to the Secretary of Labor. Accordingly, this exemption is being issued solely by the Department.

On October 15, 2021, the Department published a notice of proposed exemption in the **Federal Register**.[2] After considering the entire record developed in connection with the Applicants' exemption application, including the information discussed below, the Department has determined to grant the exemption subject to the conditions described below. The exemption provides only the relief specified in its text and does not provide relief from violations of any law other than the prohibited transaction provisions of ERISA expressly stated herein. The Department makes the requisite findings under Code section 4975(c)(2) that the exemption is (1) administratively feasible, (2) in the interest of the plans and their participants and beneficiaries, and (3) protective of the rights of the plans' participants and beneficiaries, so long as all of the exemption conditions are met. Accordingly, affected parties should be aware that the conditions incorporated in this exemption are, taken as a whole, necessary for the Department to grant the relief requested by the Applicants. Absent these or similar conditions, the Department would not have granted this exemption.

Background

1. As discussed in further detail in the notice of proposed exemption, and described below, JPMS and JPMIM previously caused or executed prohibited principal transactions on behalf of certain plan clients covered by the Employee Retirement Income Security Act of 1974 (ERISA Plan Clients) and on behalf of certain plan clients covered only by the Internal Revenue Code of 1986 (Non-ERISA Plan Clients).[3] The Applicants previously corrected the ERISA Plan Client-related prohibited transactions under the Department's Voluntary Fiduciary Compliance Program (the VFC Program) and received ''no action letters.''[4]

2. The VFC Program is not available to correct prohibited transactions involving non-ERISA plans. Therefore, the Applicants requested an exemption for JPMS and JPMIM to correct the prohibited principal transactions that involved their Non-ERISA Plan Clients (the Covered Transactions).

The Covered Transactions Involving JPMIM[5]

3. A total of 3,989 trades of securities issued by third parties were executed for the Chase Wealth Management line of business (the CWM Wrap Program) on a principal basis. According to the Applicants, 3,985 of the trades were sales by a Non-ERISA Plan Client to a counterparty (a JPM Counterparty) affiliated with JPMorgan Chase & Co. (JPMorgan), with an aggregate sales price of $2,682,332.34 (the JPMIM Sales Transactions),[6] and four trades were purchases by a Non-ERISA Plan Client from a JPM Counterparty (the JPMIM Purchase Transactions) with an aggregate purchase price of $46,940.55. The purchased shares had not been re-sold by the Non-ERISA Plan Client as of the date the transactions were corrected.[7] The Applicants represent that JPMIM and JPMS endeavored to correct the prohibited transactions as quickly as possible in the manner described under the ''Covered Transaction Corrections'' heading of the proposed exemption.[8]

4. The Applicants represent that the trades did not result in any commissions being paid by the Non-ERISA Plan Clients to JPMIM or its affiliates. Rather, the trades were executed under the CWM Wrap Program, under which all clients pay a wrap fee (*i.e.,* a comprehensive charge) that covered all of the investment advisory-related and transactional services provided by JPMorgan to such accounts. As a result, no additional compensation was paid in connection with either the JPMIM Sales Transactions or the JPMIM Purchase Transactions. The Applicants represent that JPMIM is no longer enabled to execute trades on JPM–X, an ''alternative trading system'' owned and operated by JPMS.

5. Further, the Applicants represent that there were no identifiable profits received by JPMIM or its affiliates in connection with any of the aforementioned transactions, because the securities traded were liquid securities that JPMorgan and its affiliates regularly hold in inventory, deal in or make a market in. In this regard, because JPMorgan is a market

[1] JPMS Brokerage and CWM are lines of business within JPMS.

[2] 86 FR 57446 (October 15, 2021).

[3] 86 FR 57446 (October 15, 2021).

[4] See 67 FR 15062 (March. 28, 2002), as updated at 71 FR 20262 (April 19, 2006).

[5] As described more fully in the proposed exemption and in Section II, below.

[6] These trades involved 3,784 Non-ERISA Plan Clients.

[7] These trades involved two Non-ERISA Plan Clients.

[8] 86 FR 57446, 57448.

maker in the liquid securities that were traded with the Non-ERISA Plan Clients, JPMorgan keeps a regular inventory of such securities to facilitate the purchase and sale of such securities, as well as other types of transactions involving such securities, with various counterparties. To illustrate, the Applicants present the following example:

Assume that there was a principal trade between JPMorgan and a Non-ERISA Plan Client involving a sale by JPMorgan of ten shares of a stock (Stock X) to the Non-ERISA Plan Client, at a fair market value of $50 per share. On the day of the sale, JPMorgan would hold thousands (and likely many times more) of Stock X shares in its inventory, and this inventory would change constantly throughout the day and from day to day as a result of transactions involving Stock X between JPMorgan and various counterparties. When JPMorgan sells ten Stock X shares to the Non-ERISA Plan Client, JPMorgan will deduct 10 Stock X shares from its inventory. However, because all of the Stock X shares in the JPMorgan inventory are the same and are fungible, it does not match the shares sold or disposed of with any previously acquired shares.

6. In the example above, it is not possible to identify the cost to JPMorgan of the specific shares that were sold to the Non-ERISA Plan Client because: (i) the Stock X shares in the JPMorgan inventory were all acquired at different prices and at different times (could be above, below or at $50 per share), and (ii) JPMorgan does not distinguish the Stock X shares sold to the Non-ERISA Plan Client from the rest of the Stock X shares in the inventory. Therefore, it is not possible to determine whether JPMorgan has earned any profit from the sale of such shares to the Non-ERISA Plan Client at $50 per share.

The Covered Transactions Involving JPMS Brokerage [9]

7. According to the Applicants, fifteen (15) trades involving JPMS Brokerage were mistakenly executed on a principal basis, although not on JPM–X. Of the fifteen (15) trades, two (2) were sales of securities [10] by a Non-ERISA Plan Client to a JPM Counterparty (the JPMS Brokerage Sales Transactions) with an aggregate sales price of $61,854.54, and thirteen (13) trades were purchases of securities by a Non-ERISA Plan Client from a JPM Counterparty (the JPMS Brokerage Purchase Transactions) with an aggregate purchase price of $557,232.08.[11] The purchased securities were subsequently sold by the Non-ERISA Plan Client before the prohibited transactions were discovered. The Applicants state that JPMS Brokerage endeavored to correct the prohibited transactions as quickly as possible in the manner described under the ''Covered Transaction Corrections'' heading of the proposed exemption.[12]

8. The Applicants represent that the trades in question did not result in any commissions being paid by the Non-ERISA Plan Clients to JPMS or its affiliates. Rather, the trades were executed under a wrap fee program, under which all clients pay a wrap fee (*i.e.,* a comprehensive charge) that covered all of the investment advisory-related and transactional services provided by JPMorgan to such accounts.[13] As a result, no additional compensation was paid in connection with either the JPMS Brokerage Sales Transactions or the JPMS Brokerage Purchase Transactions.

9. Further, the Applicants represent that there were no identifiable profits received by JPMS or its affiliates in connection with any of the aforementioned transactions, because the securities traded were liquid securities that JPMorgan and its affiliates regularly hold in inventory, deal in or make a market in. The Applicants state their explanation above (as to why there were no identifiable profits received by JPMIM or its affiliates with respect to the JPMIM Sales Transactions) also applies here (as to why there were no identifiable profits paid to JPMS with respect to the JPMS Brokerage Sales Transactions and JPMS Brokerage Purchase Transactions).

No Intent To Profit From Trades

10. The Applicants represent that JPMorgan did not cause the principal trades in question with the Non-ERISA Plan Clients with an intent to profit from such trades. The Applicants represent that the trades were executed by mistake and the execution was not motivated by the receipt of any profit or other compensation by JPMorgan.

11. The Applicants state that all principal trades with the Non-ERISA Plan Clients were executed at fair market value and achieved best execution, and, as a result of the correction process that JPMorgan undertook, all of the affected Non-ERISA Plan Clients were restored economically to the positions that they would have been in had the principal trades not occurred (or, in certain cases, to positions that are more economically favorable than the positions they would have been in).

12. In addition, the Applicants represent that with respect to the trades executed by JPM–X, which represented the vast majority of the principal trades in question, JPM–X was set up structurally so that all executions must be at or within the National Best Bid and Offer (NBBO) and there was a less than 1% chance (based on volume of shares traded) that any execution would be against a JPMorgan principal account, further indicating that there was no intention on the part of JPMorgan to take advantage of the Non-ERISA Plan Clients in connection with these trades.

The Proposed Exemption

13. On October 15, 2021, the Department of Labor (the Department) published a proposed exemption that would permit the Covered Transactions if the conditions therein were met.[14] Among these conditions, the Applicants were required to apply the same conditions to correct the Covered Transactions that they applied to correct the transactions involving their ERISA Plan Clients under the VFC Program. In addition, an independent fiduciary, Evercore Trust Company, N.A. (Evercore),[15] was required to determine that that the correction methodologies utilized to correct the transactions: (a) were sufficient to return each affected Non-ERISA Plan Client to at least the position it would have been in had the Covered Transaction not occurred; (b) provided Non-ERISA Plan Clients with a greater benefit than other correction methodology alternatives, consistent with the VFC Program; and (c) were properly applied based on a review of a representative sample of the corrections selected at random by Evercore.

14. The proposed exemption invited all interested persons, including current participants and beneficiaries of the Plans, to submit comments or requests for a hearing to the Department within 90 days of the date of publication. The Applicants agreed to provide notice to interested persons (NTIP) by U.S. mail to the beneficial owner of each Non-ERISA Plan Client affected by the Covered Transactions, as defined in

[9] As described in the proposed exemption and in Section II, below.

[10] These trades involved two non-ERISA Plan Clients.

[11] These trades involved seven Non-ERISA Plan Clients.

[12] 86 FR 57446, 57448.

[13] The Applicant notes that the Covered Transactions involving JPMS Brokerage were technically executed under a different wrap fee program that does not have an official name but is similar to the CWM Wrap Program.

[14] 86 FR 57446.

[15] Evercore sold its institutional trust and independent fiduciary business to Newport Group Inc. and its subsidiary, Newport Trust Company (NTC). Since October 19, 2017, NTC has served as the independent fiduciary in connection with this proposed exemption.

Section II, below, within 60 days of the publication of the notice of proposed exemption in the **Federal Register** (Notice of Proposed Exemption) and that the NTIP would include a copy of the Notice of Proposed Exemption. Throughout the comment period, the Department received several requests from the recipients of the NTIP to explain the proposed transactions. It was during these conversations that the Department was informed that the Notice of Proposed Exemption had not been included in the NTIP. The Department contacted the Applicants who confirmed that there was an error in the mailing which excluded the Notice of Proposed Exemption from the NTIP.

15. To ensure interested persons would receive full notice and have sufficient time to provide their comments to the Department, the Applicants agreed that a second notice to interested persons (the Second NTIP) would be delivered to all Non-ERISA Plan Clients along with a copy of the Notice of Proposed Exemption. On March 22, 2022, the Applicants informed the Department that the Second NTIP dated March 14, 2022, was mailed via U.S. first-class mail to the beneficial owner of each Non-ERISA Plan Client affected by the Covered Transactions.[16] Accordingly, the Department extended the comment period through April 18, 2022.[17]

Comments

16. During the comment period, the Department received one written comment from the Applicants that requested certain changes to the proposed exemption's operative language and Summary of Facts and Representations. The Applicants' comments and the Department's responses thereto are discussed below. The Department did not receive any requests for a public hearing.

Applicants' Requested Revisions to Operative Language

17. *Requested Clarification and Change to Section I of the Proposed Exemption.* On page 57450 of the proposed exemption, the first sentence of Section I states that: ''If the proposed exemption is granted, the sanctions resulting from the application of Code section 4975, by reason of Code section 4975(c)(1)(A), (D) and (E), shall not apply, effective December 14, 2010, until September 16, 2013, to certain principal trades involving J.P. Morgan Securities LLC (JPMS), J.P. Morgan Investment Management Inc. (JPMIM), J.P. Morgan Securities (JPMS Brokerage), and Chase Wealth Management (CWM) (collectively, the Applicants), and certain of their client plans that are subject to Code section 4975 but covered by not Title I of ERISA (the Non-ERISA Plan Clients).''[18]

The Applicants request that the Department clarify that JPMS Brokerage and CWM are lines of business within JPMS to be consistent with how JPMS Brokerage and CWM are introduced in the proposed exemption's Summary of Facts and Representations. Further, the Applicants request that the phrase: ''but covered by not Title I of ERISA'' be changed to read: ''but not covered by Title I of ERISA,'' for clarity.

Department's Response: After considering the Applicants' comments, the Department has revised Section I of the grant notice as requested.

18. *Requested Change to Section II of the Proposed Exemption.* On page 57450 of the proposed exemption, the first sentence of Section II(a) states that: ''For purposes of this proposed exemption, the term ''Covered Transaction means: . . .,'' and then lists a series of transactions.

The Applicants suggest changing the term, ''Covered Transaction'' in the sentence, which is the introductory paragraph of this section, to ''Covered Transactions'' (*i.e.,* from singular to plural), because there was more than one transaction.

Department's Response: After considering the Applicants' comment, the Department has made a corresponding revision to the introductory paragraph of Section II of the grant notice as requested.

19. *Requested Change to Section II(a) of the Proposed Exemption.* On page 57450 of the proposed exemption, the first sentence of Section II(a) states: ''3,989 trades of securities issued by third-parties that were executed on a principal basis for certain JPMS-sponsored wrap fee programs under the Chase Wealth Management line of business (*i.e.,* the CWM Wrap Program) on or about July 27 and July 30, 2012.''

The Applicants request changing the phrase: ''on or about'' to the word: ''on,'' as the dates listed are the exact dates on which the transactions occurred.

Department's Response: After considering the Applicant's request, the Department has revised Section II(a) of the grant notice to reflect this change.

20. *Requested Change to Section III(g) of the Proposed Exemption.* On page 57450 of the proposed exemption, Section III(g) states: ''The Covered Transactions were conducted using trading systems and procedures designed to result in trades being conducted at prices that are as favorable as possible to the Non-ERISA Plan Clients under prevailing market conditions, and were in fact conducted at terms and prices no less favorable to the Non-ERISA Plan Clients than the prices the financial advisers could have obtained for the Non-ERISA Plan Clients by conducting trades in arm's-length transactions with third-party market participants; . . .''

The Applicants suggest changing the phrase in Section III(g) of the proposal that reads ''than the prices the financial advisers'' to the phrase: ''than [the prices] the Applicants'' to be more precise.

Department's Response: After considering the Applicants' comment, the Department has revised Section III(g) of the grant notice to reflect this change as requested.

21. *Change to Section IV of the Proposed Exemption.* The Applicants and the Department discussed making certain changes to the recordkeeping provision in Section IV of this exemption, which requires the Applicants to maintain, or cause to be maintained, for a period of six (6) years from the date of any Covered Transaction, such records as are necessary to enable the persons described in Section IV(b) to determine whether the conditions of this exemption have been met. Specifically, the Applicants requested a modification to the verb tense in Section IV of the proposed exemption to reflect that, in their view, the recordkeeping period had passed. In response, the Department informed the Applicants that it intended to modify Section IV so that the recordkeeping requirement would be effective for six (6) years from the publication date of the exemption.

The Applicants raised several concerns in response, including that the Applicants may not have all the records required under Section IV, because of the passage of time between the Covered Transactions and the publication date of the exemption. In this regard, the Applicants were not aware such records would be required to be maintained for a longer period than is required in similar, prior granted retroactive exemptions, which is typically six (6)

[16] The Department considers the Second NTIP delivery to be completed three days following the March 14, 2022, mailing via U.S. first-class mail.

[17] Because the requisite 30-day comment period would end on the weekend (Saturday, March 16, 2022), the Department added an additional two days to the comment period to ensure that interested persons had a sufficient opportunity to comment.

[18] 86 FR 57446,57450. Please note that all references to page numbers of the proposed exemption refer to the version that was published in the **Federal Register** on October 15, 2021.

years from the date of the covered transactions. Nor did the Applicants learn about the Department's intended modification until after the Applicants submitted their comment during the comment period. Finally, the Applicants state that most of the individuals who are familiar with the records associated with the Covered Transactions are no longer employed with the Applicants, and it would be logistically challenging to locate and retrieve such records as more time progresses.

In light of the Department's intent for the recordkeeping period to begin on the publication date of the exemption, the Applicants request that Section IV(a) be modified slightly to require the Applicants to ''use commercially reasonable efforts to (i) identify such records, to the extent they are available to the Applicants as of the date of publication of this final exemption in the **Federal Register**, as are necessary to enable the persons described in Section IV(b)(1) to determine whether the conditions of this exemption have been met and (ii) maintain, or cause to be maintained (including on behalf of the Applicants by any agent, advisor or other service provider to the Applicants) such records, for a period of six (6) years from the date this final exemption is published in the **Federal Register**.'' Furthermore, the Applicants request that the exemption requires that record requests be made ''upon reasonable advance request,'' due to the logistical challenges the Applicant may confront in making such records available for review.

Department's Response: The Department views the change to the recordkeeping requirement in Section IV, requiring the Applicants to maintain such records for six (6) years beginning on the publication date of the exemption, as necessary to allow the individuals referenced in Section IV(b) to verify the Applicants' compliance with the exemption conditions and their representations submitted to support the application. The present-tense language in Section IV of the proposed exemption could have had the effect of rendering the recordkeeping requirement meaningless and frustrated the ability of the parties described in Section IV(b)(1) to verify that the Applicants have adhered to the exemption conditions.

However, the Department is also cognizant that the Applicants may not have retained all of the records referenced in Section IV(a) due solely to the passage of time since the Covered Transactions occurred, and that the Applicants did not anticipate the Department would include a recordkeeping requirement that would extend the period the records were required to be maintained from the publication date of the final exemption rather than the date the Covered Transactions covered transactions occurred.

Based on conversations with NTC, the independent fiduciary in connection with the exemption, the Department understands that NTC has retained the records it relied on to review the Applicants' corrections of the Covered Transactions and make any determinations required under the exemption.[19] Based upon this understanding, as well as representations by the Applicants regarding the challenges they confronted in maintaining the records several years after the Covered Transactions occurred, the Department views the Applicants' proposed change of the recordkeeping provision as a reasonable modification to the proposed exemption, provided that, if the Applicants do not themselves possess any records necessary to comply with Section IV of the exemption, the Applicants will obtain such records from the independent fiduciary.

Other Requested Revisions

22. *Minor Revisions.* At the Applicants' request, the Department made several minor, non-substantive revisions to the proposed exemption's title and Summary of Facts and Representations. The Department does not discuss the revisions in this grant notice but notes that the requested revisions may be found in the exemption application file which is available through the Department's Public Disclosure Office.[20]

23. *Other Clarifications.* On its own motion, the Department made several minor and non-substantive revisions that are intended to clarify the operative language of the exemption.

24. Accordingly, after considering the entire record developed in connection with the Applicant's exemption request, and in consideration of: (a) the exemption's protective conditions; (b) the corrective payments made to the Non-ERISA Plan Clients; and (c) Evercore's review of the corrections to the Covered Transactions, the Department has determined to grant this exemption consistent with the requirements of Code section 4975(c)(2).

25. The complete application file (D–11963) is available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, Room N–1515, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210. For a more complete statement of the facts and representations supporting the Department's decision to grant this exemption, refer to the notice of proposed exemption published on October 15, 2021, at 86 FR 57446.

General Information

The attention of interested persons is directed to the following:

(1) The fact that a transaction is the subject of an exemption under ERISA section 408(a) and/or Code section 4975(c)(2) does not relieve a fiduciary or other party in interest or disqualified person from certain requirements of other ERISA and/or Code provisions, including any prohibited transaction provisions to which the exemption does not apply and the general fiduciary responsibility provisions of ERISA section 404, which, among other things, require a fiduciary to discharge their duties respecting the plan solely in the interest of the plan's participants and beneficiaries and in a prudent fashion in accordance with ERISA section 404(a)(1)(B); nor does it affect the requirement of Code section 401(a) that requires plans to operate for the exclusive benefit of the employees of the employer maintaining the plan and their beneficiaries.

(2) As required by ERISA section 408(a) and/or Code section 4975(c)(2), the Department hereby finds that the exemption is: (a) administratively feasible; (b) in the interests of the affected plan and its participants and beneficiaries; and (c) protective of the rights of the participants and beneficiaries of such plan.

(3) This exemption is supplemental to, and not in derogation of, any other applicable ERISA and/or Code provisions, including statutory or administrative exemptions and transitional rules. Furthermore, the fact that a transaction is subject to an administrative or statutory exemption is not dispositive of determining whether the transaction is in fact a prohibited transaction.

(4) The availability of this exemption is subject to the express condition that the material facts and representations contained in the application accurately describe all material terms of the

[19] NTC confirmed to the Department that it has maintained the records associated with the services it provided to the Applicants in accordance with its own record retention policies and procedures and would provide them to the Applicants if necessary to satisfy the exemption conditions.

[20] The complete application file (D–11963) is available for public inspection in the Public Disclosure Room of the Employee Benefits Security Administration, Room N–1515, U.S. Department of Labor, 200 Constitution Avenue NW, Washington, DC 20210.

transactions that are the subject of the exemption are true and accurate at all times.

Accordingly, the Department grants the following exemption under the authority of Code section 4975(c)(2) and in accordance with the procedures set forth in 29 CFR part 2570, subpart B (76 FR 66637, 66644, October 27, 2011):

Exemption

Section I. Covered Transactions

The sanctions resulting from the application of Code section 4975, by reason of Code section 4975(c)(1)(A), (D) and (E), shall not apply, effective December 14, 2010, until September 16, 2013, to certain principal trades involving J.P. Morgan Securities LLC (JPMS), J.P. Morgan Investment Management Inc. (JPMIM), J.P. Morgan Advisors (formerly, J.P. Morgan Securities; JPMS Brokerage), and Chase Wealth Management (CWM) (collectively, the Applicants), and certain of their client plans that are subject to Code section 4975 but not covered by Title I of ERISA (the Non-ERISA Plan Clients).[21] These principal transactions resulted in the Non-ERISA Plan Clients purchasing or selling securities from or to the Applicants (the Covered Transactions, as defined in Section II, below).

This exemption is subject to the conditions set forth below in Sections III and IV.

Section II. Definition of Covered Transactions

For purposes of this proposed exemption, the term ''Covered Transactions'' means:

(a) 3,989 trades of securities issued by third parties that were executed on a principal basis for certain JPMS-sponsored wrap fee programs under the Chase Wealth Management line of business (*i.e.,* the CWM Wrap Program) on July 27 and July 30, 2012. Of these trades: (1) 3,985 of the trades involved sales by a Non-ERISA Plan Client to a counterparty affiliated with JPMorgan Chase & Co. (a JPM Counterparty), with an aggregate sales price of $2,682,332.34 (*i.e.,* the JPMIM Sales Transactions); and (2) four (4) of the trades involved purchases by a Non-ERISA Plan Client from a JPM Counterparty (*i.e.,* the JPMIM Purchase Transactions) and the purchased shares, with an aggregate purchase price of $46,940.55, had not been re-sold by the Non-ERISA Plan Client as of the date the transactions were corrected; and

(b) fifteen (15) trades involving JPMS Brokerage that were executed on a principal basis on December 14, 2010, January 13, 2011, February 3, 2012, December 31, 2012, August 22, 2013, and September 16, 2013. Of these trades: (1) two (2) involved sales of securities with an aggregate sales price of $61,854.54 by a Non-ERISA Plan Client to a JPM Counterparty (*i.e.,* the JPMS Brokerage Sales Transactions); and (2) thirteen (13) involved purchases of securities by a Non-ERISA Plan Client from a JPM Counterparty (*i.e.,* the JPMS Brokerage Purchase Transactions), with an aggregate purchase price of $557,232.08, that were purchased and subsequently sold by the Non-ERISA Plan Client before the prohibited transactions were discovered.

Section III. Specific Conditions

(a) The Applicants corrected the Covered Transactions in a manner that was: (1) consistent with the relevant requirements set forth in the Department's Voluntary Fiduciary Correction Program (the VFC Program); and (2) consistent with the Applicants' corrections of similar prohibited transactions involving its ERISA plan clients, as described in their VFC Program applications, dated December 31, 2014 (the VFC Program Applications);

(b) The Applicants received ''no action letters'' from the Department in connection with their VFC Program Applications;

(c) An independent fiduciary, Evercore Trust Company, N.A. (Evercore), reviewed the Applicants' corrections of the Covered Transactions;

(d) Evercore confirmed that the methods utilized to correct the Covered Transactions were properly applied to the Covered Transactions and sufficient to return each affected Non-ERISA Plan Client to at least the same position it would have been in had the Covered Transactions not occurred;

(e) The Non-ERISA Plan Clients did not pay any additional compensation with respect to the Covered Transactions, because such transactions were executed under a wrap program under which all clients pay a comprehensive wrap fee covering all the investment advisory-related and transactional services provided to such accounts (the Wrap Program);

(f) The Applicants promptly credited or issued a check to each Non-ERISA Plan Client to whom a corrective payment was due after discovering the Covered Transactions;

(g) The Covered Transactions were conducted using trading systems and procedures designed to result in trades being conducted at prices that are as favorable as possible to the Non-ERISA Plan Clients under prevailing market conditions, and were in fact conducted at terms and prices no less favorable to the Non-ERISA Plan Clients than the prices the Applicants could have obtained for the Non-ERISA Plan Clients by conducting trades in arm's-length transactions with third-party market participants;

(h) The Covered Transactions were not part of an agreement, arrangement or understanding designed to benefit a disqualified person as defined in Code section 4975(e)(2);

(i) The Applicants did not take advantage of the relief provided by the VFC Program and Prohibited Transaction Exemption 2002–51 for three (3) years before the date the Applicants' submitted the VFC Program Applications;[22]

(j) The Applicants and their affiliates did not receive any additional direct or indirect fee or commission in connection with the Covered Transactions, because such transactions were executed under a Wrap Program;

(k) The JPM Counterparties to the Non-ERISA Plan Clients did not receive any identifiable direct or indirect profit or compensation from the Covered Transactions;

(l) The Covered Transactions were inadvertent, executed at fair market value, and achieved best execution, and were not motivated by the receipt of any profit or other compensation;

(m) All of the securities traded were liquid securities that JPMorgan and its affiliates regularly held in inventory, dealt in, or made a market in;

(n) No contractual provisions purported to give Evercore or Newport Trust Company (*i.e.,* NTC) a right to indemnification, in whole or part, by a party related to the Applicants, for negligence or breach of federal or state law responsibilities by Evercore or NTC, with respect to any task performed by Evercore or NTC pursuant to the Applicants' exemption request; and

(o) All of the facts and representations set forth in the Summary of Facts and Representations are true and accurate.

Section IV. General Conditions

(a) The Applicants shall use commercially reasonable efforts to (i)

[21] JPMS Brokerage and CWM are lines of business within JPMS.

[22] PTE 2002–51 Section II. F(1) provides that ''[w]ith respect to any transaction described in Section I., the applicant has not taken advantage of the relief provided by the VFC Program and this exemption for a similar type of transaction(s) identified in the current application during the period which is three years prior to submission of the current application''. 67 FR 70623 (November 25, 2002), as amended, 71 FR 20135 (April 19, 2006).

identify such records as are necessary to enable the persons described in Section IV(b)(1) to determine whether the conditions of this exemption have been met, to the extent such records are available to the Applicants or NTC, the independent fiduciary, as of the date of publication of this final exemption in the **Federal Register**, and (ii) maintain, or cause to be maintained (including to be maintained on behalf of the Applicants by any agent, advisor or other service provider to the Applicants), such records for a period of six (6) years from the date of publication of this final exemption in the **Federal Register**, except that:

(1) A separate prohibited transaction shall not be considered to have occurred if the records identified in Section IV(a) are lost or destroyed before the end of the six-year period due to circumstances beyond the control of Applicants; and

(2) No disqualified person with respect to a Non-ERISA Plan Client, other than the Applicants, is subject to excise taxes imposed by Code section 4975 if such records are not maintained or made available for examination as required by section IV(b)(1).

(b)(1) Except as provided in section IV(b)(2), the records referred to in section IV(a) are unconditionally available upon reasonable advance request at their customary location for examination during normal business hours by:

(A) any duly authorized employee or representative of the Department, the Internal Revenue Service, or the Securities and Exchange Commission;

(B) any fiduciary of any Non-ERISA Plan Client that engaged in a Covered Transaction, or any duly authorized employee or representative of such fiduciary; or

(C) any owner or beneficiary of a Non-ERISA Plan Client that engaged in a Covered Transaction or a representative of such owner or beneficiary.

(2) None of the persons described in sections IV(b)(1)(B) and (C) shall be authorized to examine the Applicants' trade secrets or privileged or confidential commercial and financial information.

(3) If the Applicants refuse to disclose records referred to in section IV(a) to any persons described in sections IV(b)(1)(B), and (C) on the basis that such information is exempt from disclosure, the Applicants shall provide a written notice advising such persons of the reasons for the refusal and that the Department may request such information within 30 days after their request.

Effective Date: This exemption is in effect from December 14, 2010, until September 16, 2013.

Signed at Washington, DC, this 24th day of July 2023.

George Christopher Cosby,

Director, Office of Exemption Determinations, Employee Benefits Security Administration, U.S. Department of Labor.

[FR Doc. 2023–16129 Filed 7–28–23; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Employment and Training Administration

Agency Information Collection Activities; Comment Request; O*NET Data Collection Program

ACTION: Notice.

SUMMARY: The Department of Labor's (DOL) Employment and Training Administration (ETA) is soliciting comments concerning a revision to a previously approved information collection request (ICR) titled ''O*NET Data Collection Program.'' This comment request is part of continuing Departmental efforts to reduce paperwork and respondent burden in accordance with the Paperwork Reduction Act of 1995 (PRA).

DATES: Consideration will be given to all written comments received by September 29, 2023.

ADDRESSES: A copy of this ICR with applicable supporting documentation, including a description of the likely respondents, proposed frequency of response, and estimated total burden, may be obtained free by contacting Lauren Fairley by telephone at (202) 693–3731 (this is not a toll-free number), TTY 1–877–889–5627 (this is not a toll-free number), or by email at *fairley.lauren@dol.gov* or by accessing *http://www.onetcenter.org/ombclearance.html.*

Submit written comments about, or requests for a copy of, this ICR by mail or courier to the U.S. Department of Labor, Employment and Training Administration—Division of National Programs Tools and Technical Assistance, 200 Constitution Avenue NW, C4526, Washington, DC 20210; by email: *fairley.lauren@dol.gov;* or by fax (202) 693–3015.

FOR FURTHER INFORMATION CONTACT: Lauren Fairley by telephone at (202) 693–3731 (this is not a toll-free number) or by email at *fairley.lauren@dol.gov.*

Authority: 44 U.S.C. 3506(c)(2)(A).

SUPPLEMENTARY INFORMATION: DOL, as part of continuing efforts to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies an opportunity to comment on proposed and/or continuing collections of information before submitting them to the Office of Management and Budget (OMB) for final approval. This program helps to ensure requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements can be properly assessed. The O*NET Data Collection Program ICR 1205–0421 received OMB Clearance on November 22, 2021.

This revision to the previously-approved ICR proposes to collect updated occupational characteristics and requirements information on an ongoing basis. Under this proposal, both selected sample sizes of business establishments and use of the Occupation Expert Methodology have been increased to offset declining response rates and the potentially lasting impacts of COVID–19 on business eligibility (see Section 15).

Selected respondents will be offered varying incentive amounts to assess the impact for reducing the potential for nonresponse bias, increasing response rates, and minimizing follow-up data collection efforts; and contacted Occupation Expert source organizations will be presented with the opportunity of a recognition program for their participation (Section 9).

Informational materials have been condensed to reduce redundancy and burden (Appendix F).

Appendix G in this ICR package differs from the 2021 Appendix G submission: the look and format of the questionnaires have been modernized to reflect current best practices for surveys, including standardization of similar background questions between the Establishment and Occupation Expert questionnaires; and updating the instructions and questions for level items to add additional clarity.

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 it is approved by OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. See 5 CFR 1320.5(a) and 1320.6.

Interested parties are encouraged to provide comments to the contact shown in the **ADDRESSES** section. Comments must be written to receive consideration, and they will be summarized and included in the request for OMB approval of the final ICR. In order to help ensure appropriate consideration, comments should mention OMB Control No. 1205–0421.

Submitted comments will also be a matter of public record for this ICR and posted on the internet, without redaction. DOL encourages commenters not to include personally identifiable information, confidential business data, or other sensitive statements/information in any comments.

DOL is particularly interested in comments that:

- 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
- 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).

Agency: DOL-ETA.

Type of Review: Revision.

Title of Collection: O*NET Data Collection Program.

Form: N/A.

OMB Control Number: 1205–0421.

Affected Public: Private sector (for-profit businesses and not-for-profit organizations); State, local and tribal governments, Federal government, Individuals or Households.

Estimated Number of Respondents: 42,415.

Frequency: Varies.

Total Estimated Annual Responses: 42,415

Estimated Average Time per Response: Varies.

Estimated Total Annual Burden Hours: 15,150270 hours.

Total Estimated Annual Other Cost Burden: $0.

Brent Parton,

Acting Assistant Secretary for Employment and Training, Labor.

[FR Doc. 2023–16130 Filed 7–28–23; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2023–0003]

National Advisory Committee on Occupational Safety and Health (NACOSH); Request for Nominations

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for nominations.

SUMMARY: OSHA invites interested persons to submit nominations for membership on the National Advisory Committee on Occupational Safety and Health (NACOSH).

DATES: Nominations for NACOSH membership must be submitted (postmarked, sent, transmitted, or received) by August 30, 2023.

ADDRESSES:

Electronically: You may submit nominations, including attachments, electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the online instructions for making submissions.

OSHA will post submissions in response to this **Federal Register** notice, including personal information, in the public docket, which will be available online. Therefore, OSHA cautions interested parties about submitting personal information such as Social Security numbers and birthdates.

Docket: To read or download submissions or other material in the docket, go to *http://www.regulations.gov.* All documents in the public docket are listed in the index; however, some documents (*e.g.,* copyrighted material) are not publicly available to read or download through *www.regulations.gov.* All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General information and technical inquiries: Ms. Lisa Long, Deputy Director, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–2049; email: *long.lisa@dol.gov.*

SUPPLEMENTARY INFORMATION: The Secretary of Labor (Labor Secretary) invites interested individuals to submit nominations for membership on NACOSH.

I. Background

The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651, 656) established NACOSH to advise, consult with, and make recommendations to the Labor Secretary and the Secretary of Health and Human Services (HHS Secretary) on matters relating to the administration of the OSH Act. NACOSH is a continuing advisory committee of indefinite duration.

NACOSH operates in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2), implementing regulations (41 CFR part 102–3), the OSH Act, and OSHA's regulations on NACOSH (29 CFR part 1912a).

The Committee meets at least two times a year (29 U.S.C. 656(a)(2)). Committee members serve without compensation, but OSHA provides travel and per diem expenses. NACOSH members serve staggered terms, unless the member becomes unable to serve, resigns, ceases to be qualified to serve, or is removed by the Labor Secretary. The term of two Health and Human Services-designated NACOSH members will expire on November 15, 2023.

II. NACOSH Membership

NACOSH is comprised of 12 members appointed by the Secretary of Labor, four of which are designated by the HHS Secretary. Accordingly, the Labor Secretary seeks committed members to serve a two-year term. If a vacancy occurs before a term expires, the Labor Secretary may appoint a new member who represents the same interest as the predecessor to serve the remainder of the unexpired term. The U.S. Department of Labor is committed to equal opportunity in the workplace and seeks a broad-based and diverse NACOSH membership.

Nominations of new members, or resubmissions of current or former members, will be accepted to fill vacancies in two categories of membership. Interested persons may nominate themselves or submit the name of another person whom they believe to be interested in and qualified

to serve on NACOSH. Nominations may also be submitted by organizations from one of the categories listed.

OSHA invites nominations for the following Health and Human Services-designated NACOSH positions:

- One (1) public representative (HHS); and
- One (1) occupational health professional representative (HHS).

III. Submission Requirements

Any individual or organization may nominate one or more qualified persons for membership on NACOSH. Nominations must include the following information:

1. The nominee's name, contact information, and current employment or position;
2. The nominee's resume or curriculum vitae, including prior membership on NACOSH and other relevant organizations and associations;
3. The categories that the nominee is qualified to represent;
4. A summary of the background, experience, and qualifications that address the nominee's suitability for membership;
5. A list of articles or other documents the nominee has authored that indicates the nominee's experience in worker safety and health; and
6. A statement that the nominee is aware of the nomination, is willing to regularly attend and participate in NACOSH meetings, and has no conflicts of interest that would preclude membership on NACOSH.

OSHA will conduct a basic background check of candidates before their appointment to NACOSH. The background check will involve accessing publicly available, internet-based sources.

IV. Member Appointment

The Labor Secretary will appoint two NACOSH members, both of which will be designated by the HHS Secretary, based on their experience, knowledge, and competence in the field of occupational safety and health (29 CFR 1912a.2). Information received through this nomination process, in addition to other relevant sources of information, will assist the Labor Secretary in appointing members to NACOSH. In selecting NACOSH members, the Labor Secretary will consider individuals nominated in response to this **Federal Register** notice, as well as other qualified individuals. OSHA will publish a list of the newly appointed NACOSH members in the **Federal Register**.

Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, authorized the preparation of this notice under the authority granted by 29 U.S.C. 656, 5 U.S.C. app. 2, 29 CFR parts 1912 and 1912a; 41 CFR part 102–3; and Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020).

Signed at Washington, DC, on July 24, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–16132 Filed 7–28–23; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–23–0009; NARA–2023–037]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: We must receive responses on the schedules listed in this notice by September 15, 2023.

ADDRESSES: To view a records schedule in this notice, or submit a comment on one, use the following address: *https://www.regulations.gov/docket/NARA-23-0009/document.* This is a direct link to the schedules posted in the docket for this notice on *regulations.gov.* You may submit comments by the following method:

- *Federal eRulemaking Portal: https://www.regulations.gov.* On the website, enter either of the numbers cited at the top of this notice into the search field. This will bring you to the docket for this notice, in which we have posted the records schedules open for comment. Each schedule has a 'comment' button so you can comment on that specific schedule. For more information on *regulations.gov* and on submitting comments, see their FAQs at *https://www.regulations.gov/faq.*

If you are unable to comment via *regulations.gov,* you may email us at *request.schedule@nara.gov* for instructions on submitting your comment. You must cite the control number of the schedule you wish to comment on. You can find the control number for each schedule in parentheses at the end of each schedule's entry in the list at the end of this notice.

FOR FURTHER INFORMATION CONTACT: Kimberly Richardson, Strategy and Performance Division, by email at *regulation_comments@nara.gov* or at 301–837–2902. For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov* or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and

consult as needed with the Federal agency seeking the disposition authority. After considering comments, we may or may not make changes to the proposed records schedule. The schedule is then sent for final approval by the Archivist of the United States. After the schedule is approved, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we made to the proposed schedule. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of State, Bureau of the Comptroller and Global Financial Services, Comprehensive Records Schedule (DAA–0059–2020–0016).
2. Department of the Treasury, Internal Revenue Service, Records of Unauthorized Records Access (DAA–0058–2023–0002).
3. Peace Corps, Agency-wide, Associate Director Records (DAA–0490–2021–0003).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2023–16137 Filed 7–28–23; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Notice of Permits Issued Under the Antarctic Conservation Act of 1978

AGENCY: National Science Foundation.

ACTION: Notice of permit issued.

SUMMARY: The National Science Foundation (NSF) is required to publish notice of permits issued under the Antarctic Conservation Act of 1978. This is the required notice.

FOR FURTHER INFORMATION CONTACT: Andrew Titmus ACA Permit Officer, Office of Polar Programs, National Science Foundation, 2415 Eisenhower Avenue, Alexandria, VA 22314; 703–292–4479; email: *ACApermits@nsf.gov*.

SUPPLEMENTARY INFORMATION: On June 30, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on August 12, 2022 to:

1. Todd McKinney, Permit No. 2023–005

On August 3, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on September 21, 2022 to:

1. Lee Welhouse—Permit No. 2023–006
2. Natasja Van Gestel—Permit No. 2023–007

On August 18, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on September 23, 2022 to:

1. Jay Rotella—Permit No. 2023–008

On September 21, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on October 20, 2022 to:

1. Becky Ball—Permit No. 2023–010

On September 26, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on October 28, 2022 to:

1. Harry Anderson—Permit No. 2023–009
2. Bill Davis—Permit No. 2023–011
3. Kristin O'Brien—Permit No. 2023–014
4. Haley Shephard—Permit No. 2023–015

On October 17, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on November 17, 2022 to:

1. Steve Wellmeier—Permit No. 2023–016

On October 13, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on November 26, 2022 to:

1. Mike Jackson—Permit No. 2023–017

On October 27, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on December 3, 2022 to:

1. Bill Muntean—Permit No. 2023–017

On November 15, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on December 29, 2022 to:

1. George Papagapitos—Permit No. 2023–019

On November 17, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on December 29, 2022 to:

1. Lyndsey Lewis—Permit No. 2023–020
2. John Dennis—Permit No. 2023–021
3. Deirdre Dirkman—Permit No. 2023–022
4. David Sagrista—Permit No. 2023–023

On November 28, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on December 29, 2022 to:

1. Nikola Bajo—Permit No. 2023–024

On December 19, 2022 the National Science Foundation published a notice in the **Federal Register** of a permit application received. The permit was issued on January 17, 2023 to:

1. Daniel Villa—Permit No. 2023–025

On December 21, 2022 the National Science Foundation published a notice

in the **Federal Register** of a permit application received. The permit was issued on January 27, 2023 to:

1. Michael Raabe—Permit No. 2023–026
2. Michael Raabe—Permit No. 2023–027
3. Michael Raabe—Permit No. 2023–028
4. Michael Raabe—Permit No. 2023–029
5. Michael Raabe—Permit No. 2023–030
6. Michael Raabe—Permit No. 2023–031
7. Michael Raabe—Permit No. 2023–032
8. Michael Raabe—Permit No. 2023–033
9. Michael Raabe—Permit No. 2023–034

Kimiko S. Bowens-Knox,

Program Analyst, Office of Polar Programs.

[FR Doc. 2023–16082 Filed 7–28–23; 8:45 am]

BILLING CODE 7555–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–195 and CP2023–199; MC2023–196 and CP2023–200; MC2023–197 and CP2023–201; MC2023–198 and CP2023–202]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 2, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
II. Docketed Proceeding(s)

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–195 and CP2023–199; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 6 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* August 2, 2023.

2. *Docket No(s).:* MC2023–196 and CP2023–200; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 7 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Gregory S. Stanton; *Comments Due:* August 2, 2023.

3. *Docket No(s).:* MC2023–197 and CP2023–201; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 8 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 2, 2023.

4. *Docket No(s).:* MC2023–198 and CP2023–202; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 1 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 25, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 2, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–16198 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 25, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 6 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–195, CP2023–199.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16176 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Express, Priority Mail, and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 25, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage® Contract 1 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–198, CP2023–202.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16174 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail, First-Class Package Service & Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 26, 2023, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail, First-Class Package Service & Parcel Select Contract 39 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–200, CP2023–204.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16170 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 24, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail Contract 782 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–194, CP2023–198.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16171 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail, First-Class Package Service & Parcel Select Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 26, 2023, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail, First-Class Package Service & Parcel Select Contract 38 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–199, CP2023–203.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16175 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 25, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 7 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–196, CP2023–200.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16172 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

POSTAL SERVICE

Product Change—Priority Mail and USPS Ground Advantage® Negotiated Service Agreement

AGENCY: Postal Service™.

ACTION: Notice.

SUMMARY: The Postal Service gives notice of filing a request with the Postal Regulatory Commission to add a domestic shipping services contract to the list of Negotiated Service Agreements in the Mail Classification Schedule's Competitive Products List.

DATES: *Date of required notice:* July 31, 2023.

FOR FURTHER INFORMATION CONTACT: Sean C. Robinson, 202–268–8405.

SUPPLEMENTARY INFORMATION: The United States Postal Service® hereby gives notice that, pursuant to 39 U.S.C. 3642 and 3632(b)(3), on July 25, 2023, it filed with the Postal Regulatory Commission a *USPS Request to Add Priority Mail & USPS Ground Advantage® Contract 8 to Competitive Product List.* Documents are available at *www.prc.gov,* Docket Nos. MC2023–197, CP2023–201.

Sean C. Robinson,

Attorney, Corporate and Postal Business Law.

[FR Doc. 2023–16173 Filed 7–28–23; 8:45 am]

BILLING CODE 7710–12–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97972; File No. SR–NYSEARCA–2023–37]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To List and Trade Shares of the COtwo Advisors Physical European Carbon Allowance Trust Under NYSE Arca Rule 8.201–E

July 25, 2023.

On May 23, 2023, NYSE Arca, Inc. filed with the Securities and Exchange Commission (''Commission''), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to list and trade shares of the COtwo Advisors Physical European Carbon Allowance Trust. The proposed rule change was published for comment in the **Federal Register** on June 12, 2023.[3] The Commission has received no comments on the proposed rule change.

Section 19(b)(2) of the Act [4] provides that within 45 days of the publication of notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding, or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day after publication of the notice for this proposed rule change is July 27, 2023. The Commission is extending this 45-day time period.

The Commission finds it appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposed rule change. Accordingly, the Commission, pursuant to section 19(b)(2) of the Act,[5] designates September 10, 2023 as the date by which the Commission shall either approve or disapprove, or institute proceedings to determine whether to disapprove, the proposed rule change (File No. SR–NYSEARCA–2023–37).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[6]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16125 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 97653 (June 6, 2023), 88 FR 38110.

[4] 15 U.S.C. 78s(b)(2).

[5] *Id.*

[6] 17 CFR 200.30–3(a)(31).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97985; File No. SR–NASDAQ–2023–022]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing of Proposed Rule Change To Create a New, Non-Trading Limited Membership Class and Impose Related Requirements for Principal Underwriting Activity

July 25, 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 July 12, 2023, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to create a new, non-trading limited membership class and impose related requirements for principal underwriting activity, as described further below. The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal 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 Rules to create a new, limited membership class for those underwriters seeking only to perform underwriting activity as the principal underwriter on the Exchange [3] (and not seeking access to trade via the Nasdaq Market Center) and require a company applying for initial listing in connection with a transaction involving an underwriter to have a principal underwriter [4] that is a member or limited member of Nasdaq.

Specifically, the Exchange proposes to amend its General Rules to: (i) add a definition of ''Limited Underwriting Member'' to General 1, Section 1; (ii) add a new, limited underwriting

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''Principal underwriter'' will have the same definition used in Rule 405 promulgated under the Securities Act of 1933 (''Securities Act''): an underwriter in privity of contract with the issuer of the securities as to which he is underwriter. Such definition provides that the term ''issuer'' in the definition of ''principal underwriter'' has the meaning given in Sections 2(4) and 2(11) of the Securities Act. 17 CFR 230.405.

[4] The Exchange proposes to apply the requirements herein to a principal underwriter (defined as an underwriter in privity of contract with the issuer of the securities as to which he is underwriter) because the definition of principal underwriter points to the lead underwriter, who is generally responsible for organizing the offering, including tasks such as determining allocation of shares and the offering price, in conjunction with the issuer. Although offerings may require more than one underwriter, or a group of underwriters known as an underwriting syndicate, the Exchange proposes to focus on the lead underwriters given the substantial role they typically play in the offering process.

membership to General 3, Section 1031; and (iii) provide an exemption from registration for certain investment banking representatives associated solely with Limited Underwriting Members in General 4, Section 1230, as described below. Finally, the Exchange proposes to amend Equity 7, Section 10 to exempt Limited Underwriting Members from being assessed a trading rights fee. In addition, the Exchange proposes to amend Rule 5210 of the Listing Rules to impose a requirement that each Company applying for initial listing in connection with a transaction involving an underwriter have a principal underwriter that is a Member or Limited Underwriting Member.

Background

In the fall of 2022, Nasdaq observed instances of unusually high price spikes immediately following the pricing of certain initial public offerings (IPOs) on the Exchange and other national securities exchanges, mostly with respect to small-cap companies whose offerings were less than $25 million. In many instances, the IPO securities that were the subject of these extreme price spikes then experienced equally dramatic price declines to a level at or below the offering price. These extreme price spikes may occur in the opening trade on an exchange, or in continuous trading on the day of, or days immediately following, the listing.

Underwriters play a critical role as gatekeepers to the capital markets in connection with the trading of newly issued securities. Unusual price volatility following IPOs of certain small-cap issuers highlights the essential role underwriters play. Nasdaq relies on underwriters to select the selling syndicate and ensure that the shares are placed in a way that is reasonably designed to allow liquid trading, consistent with Nasdaq's listing requirements, and the successful introduction of the company to the marketplace. In a recent Equity Regulatory Alert,[5] Nasdaq highlighted the important role of underwriters as gatekeepers in the IPO process and the applicability of market rules and the federal securities laws. The Financial Industry Regulatory Authority (FINRA) and the New York Stock Exchange (NYSE) published similar alerts at the same time.[6] In Nasdaq's Equity Regulatory Alert, the Exchange also noted:

Nasdaq members, as well as the members of other self-regulatory organizations, that underwrite IPOs, and that play other roles in the offering process, should expect a heightened focus when an IPO experiences unusual price movements. Nasdaq Regulation will continue to investigate to determine whether such members have complied with applicable rules designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest. Areas of focus will include suspected manipulation and, beyond manipulation, whether the members are complying with their obligation to observe high standards of commercial honor and just and equitable principles of trade pursuant to Nasdaq Rule General 9, Section 1(a). That rule sets forth a standard intended to encompass a wide variety of conduct that may operate as an injustice to investors or other participants in the marketplace.[7]

Notwithstanding the important role of underwriters, Nasdaq does not currently require underwriters of companies that are going public on the Exchange to be Members of the Exchange. As such, Nasdaq does not have authority to require responses to investigative inquiries or to enforce its Rules directly against non-member underwriters.[8]

Nasdaq proposes creating a new, limited membership class and requiring underwriters involved in Nasdaq-listed IPOs to be Members or Limited Underwriting Members in order to serve as a principal underwriter of an IPO on the Exchange. By creating a new, limited membership class, Nasdaq would provide those firms seeking only to perform principal underwriting activity on the Exchange (and not seeking access to trade via the Nasdaq Market Center) the option of selecting a membership that is less burdensome *(i.e.,* to become a Limited Underwriting Member rather than a Member).[9]

Proposed Changes to Listing Rules

The proposed rule change primarily impacts membership rules and other non-listing rules, which would apply to the underwriters themselves. However, as part of the proposal, Nasdaq would impose a new requirement in its Listing Rules at 5210(l), requiring each Company applying for initial listing in connection with a transaction involving an underwriter to have a principal underwriter that is a Member or Limited Underwriting Member of Nasdaq. In proposed Rule 5210(l), the Exchange would also specify that ''principal underwriter'' shall have the same definition used in Rule 405 promulgated under the Securities Act.[10] The rule would cross reference the definition of ''Limited Underwriting Member,'' which is proposed to be added at General 1, Section 1, and would define Limited Underwriting Member to mean a broker or dealer admitted to limited underwriting membership in Nasdaq.

Proposed Changes to General Rules

Within its General Rules, the Exchange proposes to amend General 1 (General Provisions), General 3 (Membership and Access), and General 4 (Registration Requirements).

The Exchange proposes to add the definition of ''Limited Underwriting Member'' to General 1, Section 1 (Definitions). As noted above, the Exchange proposes to define Limited Underwriting Member to mean a broker or dealer admitted to limited underwriting membership in Nasdaq.

The Exchange proposes to add the new category of membership to General 3, Section 1031, within which the Exchange proposes to include information about persons eligible to become Limited Underwriting Members, Limited Underwriting Member access to the Exchange, and rules applicable to Limited Underwriting Members.

The Exchange would specify in General 3, Section 1031(a), that (i) any registered broker or dealer shall be eligible for limited underwriting membership in the Exchange, except such registered brokers or dealers as are excluded under paragraph (b) of Rule 1002;[11] and (ii) any person shall be

[5] *https://www.nasdaqtrader.com/MicroNews.aspx?id=ERA2022-9.*

[6] *https://www.nyse.com/publicdocs/nyse/markets/nyse/rule-interpretations/2022/NYSER_Reg_Memo_-_Regulatory_Scrutiny_in_Connection_with_IPOs_(2022.11.17_final).pdf; https://www.finra.org/rules-guidance/notices/22-25.*

[7] *Supra* note 5.

[8] Nasdaq does, however, have broad discretionary authority over the initial and continued listing of securities in Nasdaq in order to maintain the quality of and public confidence in its market, to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and to protect investors and the public interest. The Exchange may request information from companies that are going public on the Exchange. The Exchange may also request information from non-Member underwriters, but they are not required to respond to these requests. As described further below, this proposal would provide the Exchange with authority to directly obtain information from Limited Underwriting Members, whether pre or post-IPO.

[9] A revised Membership Application is attached [sic] as *Exhibit 3,* in which Nasdaq proposes to add a category for Limited Underwriting Members and clarify that Limited Underwriting Members are not subject to the requirement to provide an NSCC account number.

[10] *Supra* note 3.

[11] In relevant part, General 3, Section 1002(b) provides that, subject to certain exceptions, no

Continued

eligible to become an Associated Person of a Limited Underwriting Member, except such persons as are excluded under paragraph (b) of Rule 1002.[12] Proposed Rule 1031(a) is consistent with the existing rules for persons eligible to become Members and Associated Persons in General 3, Rule 1002(a).

The Exchange proposes to state, in General 3, Section 1031(b) that (i) a limited underwriting membership provides no rights to transact on the Exchange and (ii) a limited underwriting membership is solely to allow a firm that is not otherwise a Member to serve as a principal underwriter for a Company seeking to list on the Exchange, pursuant to Rule 5210(l).

Nasdaq proposes applying a limited ruleset to this newly proposed limited membership class.[13] Specifically, the Exchange proposes to apply only the following rules to Limited Underwriting Members: General 1 (General Provisions); General 2 (Organization and Administration), with the exception of Sections 6(a) and 22; General 3 (Membership and Access); General 4 (Registration Requirements); General 5 (Discipline), with the exception of Rules 8211 and 9557; General 9 (Regulation), Sections 1 and 20; and Equity 7, Section 10 (Pricing Schedule, Membership Fees). The Exchange would specify the aforementioned rules applicable to this new membership class in General 3, Section 1031(c)(1). With the proposal, the Exchange aims to apply only those rules it deems appropriate to a firm serving as a principal underwriter, including those rules it deems critical to such firms.

The Exchange proposes to apply General 1 to Limited Underwriting Members because General 1 provides defined terms that would be applicable to Limited Underwriting Members and, as explained above, the proposed rule change would also add a definition (''Limited Underwriting Member'') to General 1.

The Exchange proposes to apply General 2 (with the exception of Sections 6(a) and 22) to Limited Underwriting Members because General 2 relates to organization and administration including requirements surrounding fees, limitations on affiliations, and a requirement for an executive representative, among other obligations. The Exchange proposes to specifically exclude General 2, Sections 6(a) and Section 22. General 2, Section 6(a) states that General Equity and Options Rules and Equity Rules shall apply to all members and persons associated with a member, which is not accurate in the case of Limited Underwriting Members. General 2, Section 22 relates to Sponsored Participants and client access to the Nasdaq Market Center via a Member, which is not applicable to underwriting activity.

The Exchange also proposes to subject Limited Underwriting Members to General 3 because General 3 contains membership rules, including an obligation to follow specified procedures for applying to be a member, making changes to membership, or terminating membership. As described herein, the proposed rule change would also add additional details regarding the limited underwriting membership to General 3, Rule 1031.

The Exchange proposes to apply General 4 to Limited Underwriting Members, which includes registration requirements that are applicable to Limited Underwriting Members. The proposal would also add an exemption within General 4, as described below.

The Exchange believes it is critical to subject Limited Underwriting Members to General 5 (with the exception of Rules 8211 and 9557), which contains the Exchange's disciplinary rules.[14] Notably, General 5, Rule 8210 provides the Exchange with authority to require information from Exchange Members. The Exchange proposes to specifically exclude General 5, Rule 8211 and Rule 9557. Rule 8211 relates to members submission of trade data. Rule 9557 relates to procedures for regulating activities under General 9, Sections 40 and 41, which incorporate FINRA Rules 4110 and 4120, which relate to FINRA carrying or clearing members. Therefore, Rule 8211 and Rule 9557 are not relevant to underwriting activity.

The Exchange also believes it is important to subject Limited Underwriting Members to General 9, Section 1 which includes general standards by which Members must abide. Specifically, of importance, General 9, Section 1(a) requires Members to observe just and equitable principles of trade. General 9, Section 20 requires Members to establish and maintain a system to supervise the activities of each registered representative and associated person that is reasonably designed to achieve compliance with applicable securities laws and regulations and with applicable Nasdaq rules. The Exchange believes it is important to apply this provision on supervision as it would provide the Exchange with authority to assess whether a Limited Underwriting Member has an adequate supervisory system and written supervisory procedures in place.

Finally, the Exchange proposes to include Equity 7, Section 10 to Limited Underwriting Members because this section includes the membership and application fees applicable to Limited Underwriting Members. The Exchange proposes to avoid applying all those Exchange rules not specified in proposed General 3, Section 1031(c)(1) to Limited Underwriting Members in an effort to impose minimal burden on Limited Underwriting Members, while still allowing the Exchange to have regulatory authority over such members. Furthermore, the Exchange believes that the Exchange's rules that Limited Underwriting Members would not be subject to under the proposal primarily relate to trading activity and are, therefore, not relevant to the activities of Limited Underwriting Members.

The Exchange proposes to include language in General 3, Section 1031(c)(1) providing that, for purposes of interpreting and applying the rules to Limited Underwriting Members, references to ''Member,'' ''Members,'' or ''membership'' shall be functionally equivalent to ''Limited Underwriting Member,'' ''Limited Underwriting Members,'' or ''limited underwriting membership'' respectively. The Exchange also proposes to include a

registered broker or dealer shall be admitted to membership, and no Member shall be continued in membership, if such broker, dealer, or Member fails or ceases to satisfy the qualification requirements established by the Rules, or if such broker, dealer, or Member is or becomes subject to a statutory disqualification, or if such broker, dealer, or Member fails to file such forms as may be required in accordance with such process as the Exchange may prescribe.

[12] In relevant part, General 3, Section 1002(b) provides that, subject to such exceptions as may be explicitly provided elsewhere in the Rules, no person shall become associated with a Member, continue to be associated with a Member, or transfer association to another Member, if such person fails or ceases to satisfy the qualification requirements established by the Rules, or if such person is or becomes subject to a statutory disqualification; and no broker or dealer shall be admitted to membership, and no Member shall be continued in membership, if any person associated with it is ineligible to be an Associated Person under this subsection.

[13] Members of the Exchange, unlike Limited Underwriting Members, are subject to all of the Exchange's Rules (which includes the limited ruleset applicable to the newly proposed limited membership class).

[14] General 5, Rule 8001 provides that the Exchange and FINRA are parties to the FINRA Regulatory Contract (often referred to as a Regulatory Services Agreement (''RSA'')) pursuant to which FINRA has agreed to perform certain functions described in the Exchange's Rules on behalf of the Exchange. The Exchange does not anticipate that the proposed rule change would have any material impact on the current RSA.

requirement, in General 3, Section 1031(c)(2), that Limited Underwriting Members and their Associated Persons shall at all times be members of FINRA.[15]

Finally, the Exchange proposes to exempt persons associated solely with a Limited Underwriting Member whose functions are related solely and exclusively to underwriting and who are registered with FINRA as an Investment Banking Representative[16] from the requirement to register with the Exchange. The Exchange proposes to add such exemption to General 4, Section 1230(4).

Proposed Change to Equity Rules

The Exchange proposes to exempt Limited Underwriting Members from the trading rights fee of $1,250 per month that is normally charged to Members because such Limited Underwriting Members would not be eligible to trade on the Exchange. Accordingly, the Exchange proposes to add language to Equity 7, Section 10(a) to specify that Limited Underwriting Members would not be charged the monthly trading rights fee. Limited Underwriting Members would be subject to a $2,000 application fee (per Equity 7, Section 10(b)) and a $3,000 yearly membership fee (per Equity 7, Section 10(a)).

Implementation

The Exchange would designate the proposed changes to be operative 60 days after publication of the Commission's approval order of SR–NASDAQ–2023–022 in the **Federal Register**. This delay will allow time for firms involved with upcoming IPOs to become Limited Underwriting Members, if they choose, and for companies planning IPOs to select alternative underwriters if their current firm is not, and does not intend to become, a Member or Limited Underwriting Member.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest, by strengthening Nasdaq's ability to carry out its oversight responsibilities. It is also consistent with Section 6(b)(7) of the Act in that it provides for a fair procedure for prohibiting or limiting any person with respect to access to services offered by the Exchange or a Member thereof.[19] As discussed above, the proposal would create a new, limited membership class for those firms seeking only to perform activity as the principal underwriter of an IPO on the Exchange (and not seeking access to trade via the Nasdaq Market Center) and require a company applying for initial listing in connection with a transaction involving an underwriter to have a principal underwriter that is a member or limited member of Nasdaq. The Exchange would apply specified rules to Limited Underwriting Members, as explained above. Such rules include general provisions and standards, membership and access rules, organization and administration rules, registration requirements, disciplinary rules, and certain fees. Creating this new membership class and subjecting principal underwriters to such specified rules supports fair and orderly markets, which protects investors and the public interest, consistent with Section 6(b)(5) of the Act. Notably, the proposal would subject Limited Underwriting Members to Nasdaq's disciplinary rules, which provides Nasdaq authority to require information from such underwriters (per General 5, Rule 8210), as well as other general rules, including the requirement to observe just and equitable principles of trade (per General 9, Section 1(a)) and the requirement to establish and maintain a system to supervise the activities of registered representatives and associated persons (per General 9, Section 20). Nasdaq believes that imposing these Nasdaq rules, as well as the other rules included in proposed Rule 1031(c)(1), on principal underwriters will strengthen Nasdaq's ability to carry out its oversight responsibilities and deter potential violative conduct, such as fraud or manipulation, thereby protecting investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed changes to the Listing Rules will apply equally to all similarly situated companies applying for initial listing in connection with a transaction involving an underwriter on the Exchange. Likewise, the proposed changes to the General and Equity Rules, including to the membership rules, will apply equally to all similarly situated Applicants and Members and they will confer no relative advantage or disadvantage upon any category of Exchange Applicant or Member. Although the Exchange proposes to subject Limited Underwriting Members to a limited set of rules, the limited underwriting membership does not confer the same benefits as a standard Exchange membership. Namely, a Limited Underwriting Member would not be permitted to transact on the Nasdaq Market Center. Therefore, applying a limited ruleset to Limited Underwriting Members is justified. All Limited Underwriting Members would be subject to the same specified rules, as noted above. Moreover, the Exchange does not expect that its proposal will have an adverse impact on competition among exchanges for members. The Exchange believes the proposed rule changes, overall, will strengthen the Exchange's ability to carry out its role and responsibilities as a self-regulatory organization and deter potential violative conduct. As such, 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.

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.

[15] Limited Underwriting Members would, therefore, be eligible to waive-in to Exchange membership, as provided for in General 3, Section 1013(b). Prospective Limited Underwriting Members would need to submit a membership application (*see supra* note 9) in which they would select ''Waive-In Membership'' for the application type and ''Limited Underwriting Member of NQX'' for the nature of intended activity. For ''waive-in'' applicants, the Exchange relies substantially upon FINRA's determination to approve the applicant for FINRA membership when the Exchange evaluates the applicant for Exchange membership.

[16] In FINRA Rule 1220(b)(5), FINRA describes the requirement for representatives to register as an ''Investment Banking Representative'' if his or her activities in the investment banking or securities business of a member involve: (i) advising on or facilitating debt or equity securities offerings through a private placement or a public offering, including but not limited to origination, underwriting, marketing, structuring, syndication, and pricing of such securities and managing the allocation and stabilization activities of such offerings, or (ii) advising on or facilitating mergers and acquisitions, tender offers, financial restructurings, asset sales, divestitures or other corporate reorganizations or business combination transactions, including but not limited to rendering a fairness, solvency or similar opinion.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(7).

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission shall: (a) by order approve or disapprove such proposed rule change, or (b) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2023–022 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2023–022. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NASDAQ–2023–022 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16110 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–148, OMB Control No. 3235–0133]

Proposed Collection; Comment Request; Extension: Rule 17a–19 and Form X–17A–19

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17a–19 (17 CFR 240.17a–19) and Form X–17A–19 under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17a–19 requires every national securities exchange and registered national securities association to file a Form X–17A–19 with the Commission and the Securities Investor Protection Corporation (''SIPC'') within 5 business days of the initiation, suspension, or termination of any member and, when terminating the membership interest of any member, to notify that member of its obligation to file financial reports as required by Exchange Act Rule 17a–5(b) (17 CFR 240.17a–5(b)). There are currently a total of 25 national securities exchanges and registered national securities associations that are potential respondents under the rule.

Commission staff anticipates that the national securities exchanges and registered national securities associations collectively will make 420 total filings annually pursuant to Rule 17a–19 and that each filing will take approximately 15 minutes. The total reporting burden is estimated to be approximately 105 total annual hours.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by September 29, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 25, 2023.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16101 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, August 3, 2023.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with

the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

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

Dated: July 27, 2023.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2023–16288 Filed 7–27–23; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97988; File No. SR–CboeEDGA–2023–012]

Self-Regulatory Organizations; Cboe EDGA Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rules To Provide Users With a Risk Setting They May Elect To Apply to Their Orders That Will Allow Them To Reject Market Orders During Continuous Trading and/or Auctions

July 25, 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 July 14, 2023, Cboe EDGA Exchange, Inc. (the ''Exchange'' or ''EDGA'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGA Exchange, Inc. (''EDGA'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposal to amend Interpretation and Policy .01 to Rule 11.10 in connection with a risk setting that Users [3] may elect to apply to their orders that will allow them to reject market orders during continuous trading and/or auctions.[4] The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/edga/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend Interpretation and Policy .01 to Rule 11.10 to allow the Exchange to offer its Users the ability to apply a risk setting to their orders that will allow them to reject market orders during continuous trading or auctions (''Market Order Check''). Pursuant to Interpretation and Policy .01 to Rule 11.10, the Exchange currently offers certain optional risk settings applicable to a User's activities on the Exchange. Specifically, pursuant to Interpretation and Policy .01(c), the Exchange currently provides Users with the controls to restrict order types or modifiers that can be utilized (including pre-market, post-market, short sales, ISOs, and Directed ISOs). When utilized, this optional risk tool acts as a risk filter by evaluating a User's orders to determine whether the orders comply with certain criteria established by the User.

Based on feedback from its Members, the Exchange now seeks to expand this risk setting to allow a User to restrict additional order types from being entered—market orders during continuous trading and/or market orders during auctions (''Market Order Check'').[5] The Market Order Check will reside at a User's port level, a User-specific logical session used to access the Exchange. A User may utilize the Market Order Check to control the acceptance of, or rejection of, its inbound market orders. Similarly, a Sponsoring Member [6] may utilize the check to control the acceptance of, or rejection of, its Sponsored Participants [7] inbound market orders. Specifically, when utilized the Market Order Check will allow a User to (1) permit market orders; (2) reject market orders during continuous trading and allow market orders during auctions, or (3) reject market orders during continuous trading and also during auctions. In the case of Sponsored Participants, the Sponsoring Member will be responsible for their

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3. *See* Rule 1.5(ee).

[4] The Exchange plans to implement the proposed rule change on a date that will be circulated in a notice from the Cboe Trade Desk to all Members.

[5] The Exchange notes that the proposed Market Order Check will treat a Market Order with a Stop Price as a regular market order. *See* Rule 11.8(a), where the term Market Order is defined as ''An order to buy and sell a stated amount of a security that is to be executed at the NBBO or better when the order reaches the Exchange''; *see also* Rule 11.8(a)(1), where the term ''Stop Price'' is defined as ''An order may include a Stop Price which will convert the order into a Market Order when the Stop Price is triggered. An order to buy converts to a Market Order when the consolidated last sale in the security occurs at, or above, the specified Stop Price. An order to sell converts into a Market Order when the consolidated last sale in the security occurs at, or below, the specified Stop Price.

[6] The term ''Sponsoring Member'' shall mean a broker-dealer that has been issued a membership by the Exchange who has been designated by a Sponsored Participant to execute, clear and settle transactions resulting from the System. The Sponsoring Member shall be either (i) a clearing firm with membership in a clearing agency registered with the Commission that maintains facilities through which transactions may be cleared or (ii) a correspondent firm with a clearing arrangement with any such clearing firm. *See* Rule 1.5(aa), definition of, ''Sponsoring Member''.

[7] The term ''Sponsored Participant'' shall mean a person which has entered into a sponsorship arrangement with a Sponsoring Member pursuant to Rule 11.3. *See* Rule 1.5(z), definition of, ''Sponsored Participant''.

Sponsored Participant's Market Order Check settings. The Market Order Check will apply only to equities orders and will not apply to market on open or market on close orders. The proposed Market Order Check is similar in nature to the Order Type/Attribution check offered by Nasdaq Stock Exchange, LLC (''Nasdaq''), which prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders.[8] While the proposed Market Order Check differs slightly from that offered by Nasdaq in that it includes functionality that prohibits the entry of both auction and non-auction market orders, the intended purpose of the control—a risk management tool designed to prevent the entry of orders that may cause undue market impact—remains the same.

Importantly, as is the case with the existing risk settings, the User, and not the Exchange, will have the full responsibility for ensuring that their orders comply with applicable securities rules, laws, and regulations. Furthermore, the Exchange does not believe that the use of the Market Order Check can replace User-managed risk management solutions, and use of the Market Order Check does not automatically constitute compliance with Exchange rules.

The Exchange proposes to make the risk setting available to its Users upon request and will not require Users to utilize the Market Order Check. The Exchange will not provide preferential treatment to Users utilizing the Market Order Check. However, the Exchange believes the Market Order Check will offer Exchange Users another option in efficient risk management of its access to the Exchange. For instance, the Market Order Check may assist some Users in mitigating the risk of receiving executions at unfavorable prices due to market fluctuations and/or available liquidity in the subject security. Similarly, the Market Order Risk Check may serve as a supplemental tool for Sponsoring Members to ensure that market orders entered by their Sponsored Participants do not unexpectedly cause undue impact to the market for a security, which may occur when the market fluctuates, and an order executes at prices significantly different from the price of the security at the time of order entry.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the proposed Market Order Check is designed to protect investors and the public interest because it will provide Users with a tool to help prevent the entry of market orders that may cause unintentional market impact, and reduce the potential for disruptive, market-wide events. The proposed Market Order Check may also assist Users in managing their financial exposure by preventing executions at unfavorable prices, thereby fostering the integrity of trading on the securities markets and helping to assure the stability of the financial system. Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Users because like each of the other Exchange's risk settings, use of the Market Order Check is optional and available to all Users, and its use is not a perquisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed Market Order Check will foster competition because it would allow the Exchange to offer a risk check that is similar to functionality being offered by Nasdaq,[11] which offers an order type/attribution check that prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders. Additionally, by providing Users with additional means to monitor and control their risk, the proposed Market Order Check may enhance proper functioning of the markets and contribute to additional competition among trading venues and broker-dealer dealers. Finally, the proposed Market Order Check will enable Users to strengthen their risk management capabilities, which, in turn, may enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposal. No written comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (A) significantly affect the protection of investors or the public interest; (b) impose any significant burden on competition; and (C) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) [13] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investor and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the 30-day operative delay will allow the Exchange to immediately offer its Users an additional means to mitigate unintended market impact, thus fostering the protection of investors and

[8] *See* Nasdaq Equity 6, Section 5. Risk Settings (b), ''Order Type/Attribution Check—This control relates to the order types or modifiers that can be utilized (including pre-market, post-market, short sales, non-auction market orders and Intermarket Sweep Orders)'', available at: *https://listingcenter.nasdaq.com/rulebook/Nasdaq/rules/Nasdaq%20Equity%206/market%20impact%20check/EQUALS/#position; see also* Securities Exchange Act Release No. 34–95495 (August 12, 2022), 87 FR 50902 (August 18, 2022) (SR–NASDAQ–2022–047) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Nasdaq Equity 6, Section 5).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 10.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

the public interest. Because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGA–2023–012 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–CboeEDGA–2023–012. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGA–2023–012 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16113 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12), (a)(59).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–21, OMB Control No. 3235–0025]

Submission for OMB Review; Comment Request; Extension: Rule 30e–1

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that, under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''Paperwork Reduction Act''), the Securities and Exchange Commission (the ''Commission'') has submitted to the Office of Management and Budget (''OMB'') a request for extension of the previously approved collection of information discussed below.

Rule 30e–1 (17 CFR 270.30e–1) under the Investment Company Act of 1940 (15 U.S.C. 80a–1 *et seq.*) (''Investment Company Act'') generally requires a registered investment company (''fund'') to transmit to its shareholders, at least semi-annually, reports containing the information that is required to be included in such reports by the fund's registration statement form under the Investment Company Act. The purpose of the collection of information required by rule 30e–1 is to provide fund shareholders with current information about the operation of their funds in accordance with Section 30 of the Investment Company Act.

Approximately 2,490 funds, with a total of approximately 10,750 portfolios, respond to rule 30e–1 annually. Based on conversations with fund representatives, we estimate that it takes approximately 84 hours to comply with the collection of information associated with rule 30e–1 per portfolio. This time is spent, for example, preparing, reviewing, and certifying the reports. Accordingly, we calculate the total estimated annual internal burden of responding to rule 30e–1 to be approximately 903,000 hours (84 hours × 10,750 portfolios). In addition to the burden hours, based on conversations with fund representatives, we estimate that the total cost burden of compliance with the information collection requirements of rule 30e–1 is approximately $31,061 per portfolio. This includes, for example, the costs for funds to prepare, print, and mail the reports. Accordingly, we calculate the total external cost burden associated with rule 30e–1 to be approximately $333,905,750.

Estimates of the average burden hours are made solely for the purposes of the Paperwork Reduction Act and are not derived from a comprehensive or even representative survey or study of the costs of Commission rules and forms. The collection of information under rule 30e–1 is mandatory. The information provided under rule 30e–1 will not be kept confidential. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The public may view 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 August 30, 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: July 25, 2023.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16100 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97987; File No. SR-CboeEDGX–2023–046]

Self-Regulatory Organizations; Cboe EDGX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rules To Provide Users With a Risk Setting They May Elect To Apply to their Orders That Will Allow Them To Reject Market Orders During Continuous Trading and/or Auctions

July 25, 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 July 14, 2023, Cboe EDGX Exchange, Inc. (the ''Exchange'' or ''EDGX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe EDGX Exchange, Inc. (''EDGX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposal to amend Interpretation and Policy .01 to Rule 11.10 in connection with a risk setting that Users [3] may elect to apply to their orders that will allow them to reject market orders during continuous trading and/or auctions.[4] The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/options/regulation/rule_filings/edgx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.3. *See* Rule 1.5(ee).

[4] The Exchange plans to implement the proposed rule change on a date that will be circulated in a notice from the Cboe Trade Desk to all Members.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend Interpretation and Policy .01 to Rule 11.10 to allow the Exchange to offer its Users the ability to apply a risk setting to their orders that will allow them to reject market orders during continuous trading or auctions (''Market Order Check''). Pursuant to Interpretation and Policy .01 to Rule 11.10, the Exchange currently offers certain optional risk settings applicable to a User's activities on the Exchange. Specifically, pursuant to Interpretation and Policy .01(c), the Exchange currently provides Users with the controls to restrict order types or modifiers that can be utilized (including pre-market, post-market, short sales, ISOs, and Directed ISOs). When utilized, this optional risk tool acts as a risk filter by evaluating a User's orders to determine whether the orders comply with certain criteria established by the User.

Based on feedback from its Members, the Exchange now seeks to expand this risk setting to allow a User to restrict additional order types from being entered—market orders during continuous trading and/or market orders during auctions (''Market Order Check'').[5] The Market Order Check will reside at a User's port level, a User-specific logical session used to access the Exchange. A User may utilize the Market Order Check to control the acceptance of, or rejection of, its inbound market orders. Similarly, a Sponsoring Member [6] may utilize the check to control the acceptance of, or rejection of, its Sponsored Participants [7] inbound market orders. Specifically, when utilized the Market Order Check will allow a User to (1) permit market orders; (2) reject market orders during continuous trading and allow market orders during auctions, or (3) reject market orders during continuous trading and also during auctions. In the case of Sponsored Participants, the Sponsoring Member will be responsible for their Sponsored Participant's Market Order Check settings. The Market Order Check will apply only to equities orders and will not apply to market on open or

[5] The Exchange notes that the proposed Market Order Check will treat a Market Order with a Stop Price as a regular market order. *See* Rule 11.8(a), where the term Market Order is defined as ''An order to buy and sell a stated amount of a security that is to be executed at the NBBO or better when the order reaches the Exchange''; *see also* Rule 11.8(a)(1), where the term ''Stop Price'' is defined as ''An order may include a Stop Price which will convert the order into a Market Order when the Stop Price is triggered. An order to buy converts to a Market Order when the consolidated last sale in the security occurs at, or above, the specified Stop Price. An order to sell converts into a Market Order when the consolidated last sale in the security occurs at, or below, the specified Stop Price. Separately, the proposed Market Order Check will treat market orders with a ROOC routing option as auction orders. As such, if a User opts to block market orders in continuous trading but allow market orders in auctions, then all market orders with a ROOC routing option will be accepted. If a User chooses to block market orders during both continuous trading and during auctions, then the Market Order Check will prohibit the entry of market orders with a ROOC routing option. The Exchange is handling market orders with a ROOC routing option to ensure that Users have a clear understanding of how the Market Order Check will operate in these scenarios. Orders with ROOC routing options are hybrid in nature and can execute in auctions or during continuous trading. As such, an order may fully execute in the auction, as well as receive no execution or receive a partial fill with the remaining shares being posted to the Exchange Book, executed on the Exchange, or routed to other destinations. Given the various iterations that a market order with a ROOC routing option may encounter, the Exchange believes much operational complexity can be avoided by treating market orders with ROOC routing options in this simplified manner. *See* Rule 11.11(g)(8), where the term ''ROOC'' is defined as ''a routing option for orders that the entering firm wishes to designate for the participation in the opening, re-opening (following a halt, suspension, or pause), or closing process of a primary listing market (Cboe BZX, NYSE, Nasdaq, NYSE America, or NYSE Arca) if received before the opening/re-opening/closing time of such market. If shares remain unexecuted after attempting to execute in the opening, reopening, or closing process, they are either posted to the EDGX Book, executed, or routed to destinations on the System routing table.''

[6] The term ''Sponsoring Member'' shall mean a broker-dealer that has been issued a membership by the Exchange who has been designated by a Sponsored Participant to execute, clear and settle transactions resulting from the System. The Sponsoring Member shall be either (i) a clearing firm with membership in a clearing agency registered with the Commission that maintains facilities through which transactions may be cleared or (ii) a correspondent firm with a clearing arrangement with any such clearing firm. *See* Rule 1.5(aa), definition of, ''Sponsoring Member''.

[7] The term ''Sponsored Participant'' shall mean a person which has entered into a sponsorship arrangement with a Sponsoring Member pursuant to Rule 11.3. *See* Rule 1.5(z), definition of, ''Sponsored Participant''.

market on close orders. The proposed Market Order Check is similar in nature to the Order Type/Attribution check offered by Nasdaq Stock Exchange, LLC (''Nasdaq''), which prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders.[8] While the proposed Market Order Check differs slightly from that offered by Nasdaq in that it includes functionality that prohibits the entry of both auction and non-auction market orders, the intended purpose of the control—a risk management tool designed to prevent the entry of orders that may cause undue market impact—remains the same.

Importantly, as is the case with the existing risk settings, the User, and not the Exchange, will have the full responsibility for ensuring that their orders comply with applicable securities rules, laws, and regulations. Furthermore, the Exchange does not believe that the use of the Market Order Check can replace User-managed risk management solutions, and use of the Market Order Check does not automatically constitute compliance with Exchange rules.

The Exchange proposes to make the risk setting available to its Users upon request and will not require Users to utilize the Market Order Check. The Exchange will not provide preferential treatment to Users utilizing the Market Order Check. However, the Exchange believes the Market Order Check will offer Exchange Users another option in efficient risk management of its access to the Exchange. For instance, the Market Order Check may assist some Users in mitigating the risk of receiving executions at unfavorable prices due to market fluctuations and/or available liquidity in the subject security. Similarly, the Market Order Risk Check may serve as a supplemental tool for Sponsoring Members to ensure that market orders entered by their Sponsored Participants do not unexpectedly cause undue impact to the market for a security, which may occur when the market fluctuates, and an order executes at prices significantly different from the price of the security at the time of order entry.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the proposed Market Order Check is designed to protect investors and the public interest because it will provide Users with a tool to help prevent the entry of market orders that may cause unintentional market impact, and reduce the potential for disruptive, market-wide events. The proposed Market Order Check may also assist Users in managing their financial exposure by preventing executions at unfavorable prices, thereby fostering the integrity of trading on the securities markets and helping to assure the stability of the financial system. Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Users because like each of the other Exchange's risk settings, use of the Market Order Check is optional and available to all Users, and its use is not a perquisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed Market Order Check will foster competition because it would allow the Exchange to offer a risk check that is similar to functionality being offered by Nasdaq,[11] which offers an order type/attribution check that prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders. Additionally, by providing Users with additional means to monitor and control their risk, the proposed Market Order Check may enhance proper functioning of the markets and contribute to additional competition among trading venues and broker-dealer dealers. Finally, the proposed Market Order Check will enable Users to strengthen their risk management capabilities, which, in turn, may enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposal. No written comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (A) significantly affect the protection of investors or the public interest; (b) impose any significant burden on competition; and (C) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b-4(f)(6) [13] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investor and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the 30-day operative delay will allow the Exchange to immediately offer its Users an additional means to mitigate unintended market impact, thus fostering the protection of investors and the public interest. Because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day

[8] *See* Nasdaq Equity 6, Section 5. Risk Settings (b), ''Order Type/Attribution Check—This control relates to the order types or modifiers that can be utilized (including pre-market, post-market, short sales, non-auction market orders and Intermarket Sweep Orders)'', available at: *https://listingcenter.nasdaq.com/rulebook/Nasdaq/rules/Nasdaq%20Equity%206/market%20impact%20check/EQUALS/#position; see also* Securities Exchange Act Release No. 34–95495 (August 12, 2022), 87 FR 50902 (August 18, 2022) (SR–NASDAQ–2022–047) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Nasdaq Equity 6, Section 5).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 10.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b-4(f)(6). In addition, Rule 19b-4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeEDGX–2023–046 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–CboeEDGX–2023–046. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeEDGX–2023–046 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16112 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12), (a)(59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97977; File No. SR–CboeBZX–2023–049]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

July 25, 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 July 12, 2023, Cboe BZX Exchange, Inc. (''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'' or ''BZX Equities'') proposes to amend its Fee Schedule. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Fee Schedule applicable to its equities trading platform (''BZX Equities'') as follows: (1) adopt a new Add Volume Tier and renumber the remaining tiers; (2) adopt a new Step-Up Tier; and (3) modifying the rates associated with certain fee codes. The Exchange proposes to implement the proposed change to its fee schedule on July 3, 2023.[3]

The Exchange first notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. More specifically, the Exchange is only one of 16 registered equities exchanges, as well as a number of alternative trading systems and other off-exchange venues that do not have similar self-regulatory responsibilities under the Exchange Act, to which market participants may direct their order flow. Based on publicly available information,[4] no single registered equities exchange has more than 15% of the market share. Thus, in such a low-concentrated and highly competitive market, no single equities

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange initially filed the proposed fee change on June 30, 2023 (SR-CboeBZX–2023–045). On July 12, 2023, the Exchange withdrew that proposal and submitted this proposal.

[4] See Cboe Global Markets, U.S. Equities Market Volume Summary, Month-to-Date (June 22, 2023), available at *https://www.cboe.com//equities/market_statistics/.*

exchange possesses significant pricing power in the execution of order flow. The Exchange in particular operates a ''Maker-Taker'' model whereby it pays credits to Members that add liquidity and assesses fees to those that remove liquidity. The Exchange's fee schedule sets forth the standard rebates and rates applied per share for orders that provide and remove liquidity, respectively. Currently, for orders in securities priced at or above $1.00, the Exchange provides a standard rebate of $0.00160 per share for orders that add liquidity and assesses a fee of $0.0030 per share for orders that remove liquidity.[5] For orders in securities priced below $1.00, the Exchange does not provide a rebate or assess a fee for orders that add liquidity and assesses a fee of 0.30% of total dollar value for orders that remove liquidity.[6] Additionally, in response to the competitive environment, the Exchange also offers tiered pricing which provides Members opportunities to qualify for higher rebates or reduced fees where certain volume criteria and thresholds are met. Tiered pricing provides an incremental incentive for Members to strive for higher tier levels, which provides increasingly higher benefits or discounts for satisfying increasingly more stringent criteria.

Add Volume Tiers

Pursuant to footnote 1 of the Fee Schedule, the Exchange currently offers various Add/Remove Volume Tiers. In particular, the Exchange offers seven Add Volume Tiers that provide Members an opportunity to receive enhanced rebates for orders yielding fee codes B,[7] V,[8] and Y[9] where a Member reaches certain add volume-based criteria offered in each tier. The Exchange now proposes to introduce a new Add Volume Tier 4 and renumber existing Add Volume Tiers 4–7. The proposed criteria of new Add Volume Tier 4 is as follows:

• Proposed Add Volume Tier 4 will provide a rebate of $0.0028 per share for qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y) where (1) Member is enrolled in at least 50 BZX-listed LMP Securities[10] for which it meets the following criteria for at least 50% of the trading days in the applicable month: (i) Member has an NBBO Time[11] ≥15% or an NBBO Size Time[12] ≥25%; and (ii) Member has a Displayed Size Time[13] ≥90%; and (2) Member is enrolled in at least 30 LMM Securities;[14] and (3) Member has an ADAV as a percentage of TCV[15] ≥0.15%.

The Exchange's proposal to introduce a new Add Volume Tier 4 is designed to provide Members with an additional way in which to receive an enhanced rebate if certain criteria are satisfied, specifically by incentivizing additional volume in securities identified by the Exchange, including BZX-listed securities. The Exchange believes that by introducing proposed Add Volume Tier 4 Members are incentivized to add displayed volume on the Exchange, thereby contributing to a deeper and more liquid market, which benefits all market participants and provides greater execution opportunities on the Exchange.

Step-Up Tiers

Pursuant to footnote 2 of the Fee Schedule, the Exchange currently offers two Step Up Tiers that provide Members an opportunity to receive an enhanced rebate from the standard rebate for liquidity adding orders that yield fee codes B, V, and Y where they increase their relative liquidity each month over a predetermined baseline. The Exchange now proposes to add a new Step-Up Tier 1. Proposed Step-Up Tier 1 would provide for the following:

• Proposed Step-Up Tier 1 would offer an enhanced rebate of $0.0028 per share for qualifying orders (*i.e.,* orders yielding fee codes B, V, or Y) where Member has a Step-Up ADAV[16] from June 2023 ≥10,000,000.

Additionally, the Exchange notes that Proposed Step-Up Tier 1 will expire no later than September 30, 2023, which the Exchange will indicate on the Exchange's fee schedule.

The Exchange notes that the Step-Up Tiers in general are designed to provide Members with additional opportunities to receive enhanced rebates by increasing their order flow to the Exchange, which further contributes to a deeper, more liquid market and provides even more execution opportunities for active market participants. Like other Step-Up Tiers, the proposed Step-Up Tier 1 is designed to give members an additional opportunity to receive an enhanced rebate for orders meeting the applicable criteria. Increased overall order flow benefits all Members by contributing towards a robust and well-balanced market ecosystem.

Fee Code Changes

The Exchange offers various fee codes for orders routed away from the Exchange. The Exchange is proposing to modify the routing fees associated with fee codes BY,[17] BJ,[18] AX,[19] AA,[20] AY,[21] P,[22] and RY[23] to match the base add or remove rate for the associated market center to which the order is routed. The rebates for fee codes BJ, AA, and P will be revised to $0.0016 per share in securities priced above $1.00.[24] The rebates for fee codes BY and AY will be revised to $0.0002 per share in securities priced above $1.00.[25] The fee for fee code RY will be revised to $0.0020 per share in securities priced above $1.00.[26] The fee for fee code AX will be revised to $0.0030 per share in securities priced above $1.00.[27] There

[5] *See* BZX Equities Fee Schedule, Standard Rates.

[6] *Id.*

[7] Orders yielding Fee Code ''B'' are displayed orders adding liquidity to BZX (Tape B).

[8] Orders yielding Fee Code ''V'' are displayed orders adding liquidity to BZX (Tape A).

[9] Orders yielding Fee Code ''Y'' are displayed orders adding liquidity to BZX (Tape C).

[10] ''LMP Securities'' means a list of securities included in the Liquidity Management Program, the universe of which will be determined by the Exchange and published in a circular distributed to Members and on the Exchange's website. Such LMP Securities will include all Cboe-listed ETPs and certain non-Cboe listed-ETPs for which the Exchange wants to incentive Members to provide enhanced market quality. All Cboe-listed securities will be LMP Securities immediately upon listing on the Exchange. The Exchange will not remove a security from the list of LMP Securities without 30 days prior notice.

[11] ''NBBO Time'' means the average of the percentage of time during regular trading hours during which the Member maintains at least 100 shares at each of the NBB and NBO.

[12] ''NBBO Size Time'' means the percentage of time during regular trading hours during which there are size-setting quotes at the NBBO on the Exchange.

[13] ''Displayed Size Time'' means the percentage of time during regular trading hours during which the Member maintains at least 2,500 displayed shares on the bid and separately maintains at least 2,500 displayed shares on the offer that are priced no more than 2% away from the NBB and NBO, respectively.

[14] ''LMM Securities'' are BZX-listed securities for which a Lead Market Maker (''LMM'') for which the Member is the LMM.

[15] ''TCV'' means total consolidated volume calculated as the volume reported by all exchanges and trade reporting facilities to a consolidated transaction reporting plan for the month for which the fees apply.

[16] ''Step-Up ADAV'' means ADAV in the relevant baseline month subtracted from current ADAV.

[17] Fee code BY is appended to orders routed to BYX using Destination Specific, TRIM or SLIM routing strategy.

[18] Fee code BJ is appended to orders routed to EDGA using TRIM or SLIM routing strategy.

[19] Fee code AX is appended to orders routed to EDGX using ALLB routing strategy.

[20] Fee code AA is appended to orders routed to EDGA using ALLB routing strategy.

[21] Fee code AY is appended to orders routed to BYX using the ALLB routing strategy.

[22] Fee code P is appended to orders routed to EDGX that add liquidity.

[23] Fee code RY is appended to orders routed to BYX that add liquidity.

[24] *See* BZX Equities Fee Schedule, Standard Rates; EDGA Equities Fee Schedule, Standard Rates.

[25] *See* BYX Equities Fee Schedule, Standard Rates.

[26] *Id.*

[27] *See* EDGX Equities Fee Schedule, Standard Rates.

are no changes to the fees or rebates associated with securities priced below $1.00.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of section 6(b) of the Act.[28] Specifically, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[29] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the section 6(b)(5)[30] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers as well as section 6(b)(4)[31] as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities.

As described above, the Exchange operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels at a particular venue to be excessive or incentives to be insufficient. The Exchange believes that its proposal to introduce a new Add Volume Tier 4 and a new Step-Up Tier 1 reflects a competitive pricing structure designed to incentivize market participants to direct their order flow to the Exchange, which the Exchange believes would enhance market quality to the benefit of all Members. The Exchange believes the proposed Add Volume Tier 4 and Step-Up Tier 1 are reasonable as they serve to incentivize Members to increase their liquidity-adding, displayed volume, which benefit all market participants by incentivizing continuous liquidity and thus, deeper, more liquid markets as well as increased execution opportunities. Particularly, the proposed incentives are designed to incentivize continuous displayed liquidity, which signals other market participants to take the additional execution opportunities provided by such liquidity. This overall increase in activity deepens the Exchange's liquidity pool, offers additional cost savings, supports the quality of price discovery, promotes market transparency, and improves market quality for all investors.

The Exchange believes the proposed changes to fee codes BY, BJ, AX, AA, AY, P, and RY are reasonable and not unfairly discriminatory as these changes will apply to all Members and do not represent a significant departure from the Exchange's general pricing structure. Indeed, the proposed changes to these fee codes are intended to match the base add or remove rates on the Exchanges affiliates.[32] The Exchange also believes the proposed Add Volume Tier 4 and Step-Up Tier 1 represent an equitable allocation of rebates and are not unfairly discriminatory because all Members are eligible for those tiers and would have the opportunity to meet a tier's criteria and would receive the proposed rebate if such criteria is met. Further, the proposed rebates are commensurate with the proposed criteria. That is, the rebates reasonably reflect the difficulty in achieving the applicable criteria as proposed. Without having a view of activity on other markets and off-exchange venues, the Exchange has no way of knowing whether this proposed rule change would definitely result in any Members qualifying for the proposed tier. While the Exchange has no way of predicting with certainty how the proposed tiers will impact Member activity, the Exchange anticipates that at least one Member will be able to satisfy the criteria proposed under proposed Add Volume Tier 4 and at least one Member will be able to satisfy the criteria proposed under proposed Step-Up Tier 1. The Exchange also notes that proposed tier/rebate will not adversely impact any Member's ability to qualify for other reduced fee or enhanced rebate tiers. Should a Member not meet the proposed criteria under the modified tier, the Member will merely not receive that corresponding enhanced rebate.

Additionally, the Exchange notes that relative volume-based incentives and discounts have been widely adopted by exchanges,[33] including the Exchange,[34] and are reasonable, equitable and non-discriminatory because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to (i) the value to an exchange's market quality and (ii) associated higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns. Competing equity exchanges offer similar tiered pricing structures, including schedules of rebates and fees that apply based upon members achieving certain volume and/or growth thresholds, as well as assess similar fees or rebates for similar types of orders, to that of the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional order flow to a public exchange, thereby promoting market depth, execution incentives and enhanced execution opportunities, as well as price discovery and transparency for all Members. As a result, the Exchange believes that the proposed changes further the Commission's goal in adopting Regulation NMS of fostering competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.''[35]

The Exchange believes the proposed rule changes do not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. Particularly, the proposed tier changes apply to all Members equally in that all Members are eligible for the proposed Add Volume Tier 4 and proposed Step-Up Tier 1, have a reasonable opportunity to meet the tiers' criteria and will receive the corresponding additional rebates if such criteria are met. Additionally, the proposed tiers are designed to attract additional order flow to the Exchange. The Exchange believes that the proposed tier criteria would incentivize market participants to direct liquidity adding displayed order flow to the Exchange, bringing with it additional execution opportunities for market participants and improved price transparency. Greater overall order flow, trading opportunities, and pricing transparency benefits all market participants on the Exchange by

[28] 15 U.S.C. 78f(b).

[29] 15 U.S.C. 78f(b)(5).

[30] *Id.*

[31] 15 U.S.C. 78f(b)(4)

[32] *Supra* notes 24–27.

[33] *See e.g.,* EDGX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[34] *See e.g.,* BZX Equities Fee Schedule, Footnote 1, Add/Remove Volume Tiers.

[35] Securities Exchange Act Release No. 51808, 70 FR 37495, 37498–99 (June 29, 2005) (S7–10–04) (Final Rule).

enhancing market quality and continuing to encourage Members to send orders, thereby contributing towards a robust and well-balanced market ecosystem.

The Exchange believes the proposal to revise the applicable fees or rebates associated with routing orders away from the Exchange does not a burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. The fees and rebates associated with routing orders away from the Exchange apply to all Members on an equal and non-discriminatory basis and Members can choose to use (or not use) the Exchange's routing functionality as part of their decision to submit order flow to the Exchange.

Next, the Exchange believes the proposed rule change does not impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. As previously discussed, the Exchange operates in a highly competitive market. Members have numerous alternative venues that they may participate on and direct their order flow, including 15 other equities exchanges and off exchange venues and alternative trading systems. Additionally, the Exchange represents a small percentage of the overall market. Based on publicly available information, no single equities exchange has more than 15% [36] of the market share. Therefore, no exchange possesses significant pricing power in the execution of order flow. Indeed, participants can readily choose to send their orders to other exchange and off-exchange venues if they deem fee levels at those other venues to be more favorable. Moreover, the Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Specifically, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [37] The fact that this market is competitive has also long been recognized by the courts. In *NetCoalition* v. *Securities and 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'. . ..''.[38] Accordingly, the Exchange does not believe its proposed fee change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act [39] and paragraph (f) of Rule 19b–4 [40] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2023–049 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR-CboeBZX–2023–049. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2023–049 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[41]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16122 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[36] *Supra* note 4.

[37] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005).

[38] *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)).

[39] 15 U.S.C. 78s(b)(3)(A).

[40] 17 CFR 240.19b–4(f).

[41] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–424, OMB Control No. 3235–0473]

Proposed Collection; Comment Request; Extension: Rule 17Ad–3(b)

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services,

100 F Street NE, Washington, DC 20549–2736

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 17Ad–3(b) (17 CFR 240.17Ad–3(b)), under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 17Ad–3(b) requires registered transfer agents to send a copy of the written notice required under Rule 17Ad–2(c), (d), and (h) to the chief executive officer of each issuer for which the transfer agent acts when it has failed to turnaround at least 75% of all routine items in accordance with the requirements of Rule 17Ad–2(a), or to process at least 75% of all items in accordance with the requirements of Rule 17Ad–2(b), for two consecutive months. The issuer may use the information contained in the notices: (1) as an early warning of the transfer agent's non-compliance with the Commission's minimum performance standards regarding registered transfer agents; and (2) to become aware of certain problems and poor performances with respect to the transfer agents that are servicing the issuer's issues. If the issuer does not receive notice of a registered transfer agent's failure to comply with the Commission's minimum performance standards, then the issuer will be unable to take remedial action to correct the problem or to find another registered transfer agent. Pursuant to Rule 17Ad–3(b), a transfer agent that has already filed a Notice of Non-Compliance with the Commission pursuant to Rule 17Ad–2 will only be required to send a copy of that notice to issuers for which it acts when that transfer agent fails to turnaround 75% of all routine items or to process 75% of all items for two consecutive months.

The Commission estimates that only one transfer agent will be subject to the third party disclosure requirements of Rule 17Ad–3(b) each year. If a transfer agent fails to meet the turnaround and processing requirements under 17Ad–3(b), it would simply send its issuer-clients a copy of the notice that had already been produced for the Commission pursuant to Rule 17Ad–2(c) or (d). The Commission estimates the requirement will take the transfer agent approximately four hours to complete. The total estimated burden associated with Rule 17Ad–3(b) is thus approximately 4 hours per year. The Commission estimates that the internal compliance cost for the transfer agent to comply with this third party disclosure requirement will be approximately $1,128 per year (4 hours × $283 per hour = $1,128). The total estimated internal cost of compliance associated with Rule 17Ad–3(b) is thus approximately $1,128 per year. There are no external costs associated with sending the notice to issuer-clients.

Written comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted by September 29, 2023.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o John Pezzullo, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 25, 2023.

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16099 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97973; File No. SR–NASDAQ–2023–024]

Self-Regulatory Organizations; The Nasdaq Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Equity 4, Rules 4752, 4753, and 4754

July 25, 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 July 19, 2023, The Nasdaq Stock Market LLC (''Nasdaq'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Equity 4, Rules 4752, 4753, and 4754[3] to clarify and restate the order in which Nasdaq prioritizes executions of Orders in its Opening, Closing, and Halt Crosses.

The text of the proposed rule change is available on the Exchange's website at *https://listingcenter.nasdaq.com/rulebook/nasdaq/rules,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend and restate portions of its Rules governing its Opening (Rule 4752) and Closing Crosses (Rule 4754) (collectively, the ''Crosses'') to clarify the existing processes for execution prioritization, including by correcting errors and omissions, as well as to clarify the Exchange's intentions for those processes. The Exchange also proposes to amend the Rule governing processing of the Halt Cross (Rule 4753) to accurately reflect the relative execution prioritization of Displayed and Non-Displayed Orders entered therein.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] References herein to Nasdaq Rules in the 4000 Series shall mean Rules in Nasdaq Equity 4.

The Exchange's Rules governing its Crosses each include a description of the priority in which the Exchange will execute Orders eligible to execute in a Cross when fewer than all such orders can be executed therein. The priority assignments are unique to each type of Cross.

With respect to the Opening and Closing Crosses, the Exchange generally assigns priority in buckets as follows, with orders executed on a price-time basis within each bucket: (1) market orders designated for the Crosses; (2) interest designated for the Crosses that is priced more aggressively than the Opening/Closing Cross Price, as applicable; (3) limit on Open/Close orders and displayed interest priced at the Opening/Closing Cross Price; and (4) non-displayed interest. All orders unexecuted in the Crosses are cancelled unless they are otherwise designated to continue trading afterwards.

The Exchange proposes to restate its Opening and Closing Cross procedures to clarify, simplify and, in certain cases, correct them so that they fully reflect the Exchange's intentions and practices. The Exchange believes that the existing Rule text is confusing in several respects. First, the existing prioritization Rules expressly differentiate between executions of certain Orders priced more aggressively than the Cross prices from those that would be priced at the Cross prices, even though the concept of price-time priority necessarily provides that Orders priced more aggressively would execute before Orders priced less aggressively. Second, the existing Rules describe, but do not always state expressly, that they prioritize execution of Displayed Orders and interest before Non-Displayed Orders. Third, the Rules do not state clearly how the System prioritizes certain Orders that are designated to either execute in the Crosses or cancel, without rebooking unaltered into the continuous market.

The Exchange proposes to restate and clarify these existing Rules for the Nasdaq Opening and Closing Crosses to address these issues, as follows.

The Exchange proposes to retain the first order execution prioritization bucket for the Nasdaq Opening Cross, at Rule 4752(d)(3)(A), which states that the System will first prioritize execution of Market on Open Orders (''MOOs'') [4] and Early Market Hours market peg orders,[5] with time as the secondary priority. However, the Exchange proposes to consolidate the next two prioritization buckets, at Rule 4752(d)(3)(B) and (C).

Under existing Rule 4752(d)(3)(B), the System prioritizes Limit on Open Orders (''LOOs''),[6] limit orders with a Time in Force (''TIF'') of Early Market Hours,[7] Opening Imbalance Only Orders (''OIOs''),[8] SDAY limit orders, SGTC limit orders, GTMC limit orders, SHEX limit orders, displayed [9] quotes, and reserve interest priced more aggressively than the Nasdaq Opening Cross price based on limit price with time as the secondary priority. Under existing Rule 4752(d)(3)(C), the System prioritizes execution of remaining LOOs and displayed interest, *i.e.,* LOO orders, OIO, Early Market Hours Orders and displayed interest of quotes, SDAY limit orders, SGTC limit orders, GTMC limit orders, and SHEX limit orders, at the Nasdaq Opening Cross price with time as the secondary priority. Nasdaq proposes to consolidate these two buckets into one, as they state essentially the same thing—that the Exchange will prioritize as a group the execution of Displayed Orders and interest, with price as the primary priority, and then within each price level, time as the secondary priority. That is, there is no reason to distinguish between Orders priced more aggressively than the Opening Cross Price from those priced at the Opening Cross Price, as the concept of price-time priority sufficiently implies that the former category of Orders will execute prior to the latter category of Orders.[10] The proposed amended Rule text also makes clear that all of the Orders in this new single prioritization bucket are either Displayed Orders or, as discussed below, are neither Displayed nor Non-Displayed Orders, but are currently treated like Displayed Orders for purposes of execution priority.[11] This includes auction-only Orders with an Immediate-or-Cancel Order Attribute (''IOC'' Orders) [12] that do not rest on the Book after entry (and thus are neither Displayed nor Non-Displayed, strictly speaking), and are designated to either execute in the Opening Cross or cancel, without rebooking unaltered into the continuous market afterwards. (OIOs are another example of such an auction-only Order that is assigned a TIF of IOC and is therefore treated as a Displayed Order for purposes of priority.) The existing prioritization language does not clearly account for such Orders, and the proposal codifies their treatment. The proposed consolidated and restated

[4] A MOO is an Order Type entered without a price that may be executed only during the Nasdaq Opening Cross at the price determined by the Opening Cross. *See* Rule 4702(b)(8).

[5] ''Early Market Hours Orders'' are those that, if entered into the System prior to 9:28 a.m. shall be treated as MOO and LOO, as appropriate, for the purposes of the Nasdaq Opening Cross. *See* Rule 4752(a)(10).

[6] A LOO is an Order Type entered with a price that may be executed only in the Nasdaq Opening Cross, and only if the price determined by the Nasdaq Opening Cross is equal to or better than the price at which the LOO Order was entered. *See* Rule 4702(b)(9).

[7] A TIF assigned to an Order means the period of time that the Nasdaq Market Center will hold the Order for potential execution. Participants specify an Order's Time-in-Force by designating a time at which the Order will become active and a time at which the Order will cease to be active. *See* Rule 4703(a). TIFs that would permit trading on the Continuous Book during Regular Market Hours include TIFs of ''Market Hours,'' ''Market Hours Day'' or ''MDAY,'' ''Market Hours Good-til-Cancelled'' or ''MGTC,'' ''System Hours,'' ''System Hours Good-til-Cancelled'' or ''SGTC,'' ''Good-til-Cancelled'' or ''GTC,'' and Extended Hours Trading or ''EXT.'' TIFs that would permit trading on the Continuous Book after Regular Market Hours include TIFs of ''System Hours,'' ''SDAY,'' ''GTC,'' and Closing Cross/Extended Hours'' or ''EXT.'' *See id.; see* Rule 4702(b)(12)(B).

[8] An OIO is an Order Type entered with a price that may be executed only in the Nasdaq Opening Cross and only against MOO Orders, LOO Orders, or Early Market Hours Orders. *See* Rule 4702(b)(10).

[9] Display is an Order Attribute that allows the price and size of an Order to be displayed to market participants via market data feeds. All Orders that are Attributable are also displayed, but an Order may be displayed without being Attributable. As discussed in Rule 4702, a Non-Displayed Order is a specific Order Type, but other Order Types may also be non-displayed if they are not assigned a Display Order Attribute; however, depending on context, all Orders that are not displayed may be referred to as ''Non-Displayed Orders.'' An Order with a Display Order Attribute may be referred to as a ''Displayed Order.'' *See* Rule 4703(k).

[10] There is also no reason for the existing Rules to state the different types of Displayed Limit Orders that this bucket contains, as all such Limit Orders are included in it. Thus, the Exchange proposes to refer to these orders collectively as ''Limit Orders.''

[11] The proposed amended Rule also addresses an oversight in the prioritization of Reserve Orders. Currently, Rule 4752(d)(3)(B) expressly sets priority for ''displayed . . . reserve interest''—which refers to the Displayed portion of Reserve Orders—priced more aggressively than the Cross Price. However, Rule 4752(d)(3)(C) does not expressly account for displayed reserve interest priced at the Opening Cross Price. Instead, the Rule merely implies that such Orders are included in (C) by referring to ''remaining . . . displayed interest.'' Market participants may find such incongruous language confusing, and the Exchange therefore the Exchange proposes to delete references to ''reserve interest'' in existing Rule 4752(d)(3)(B) and the ''interest of quotes'' in existing Rule 4752(d)(3)(C) in favor of the phrase ''the Displayed size of Reserve Orders.''

[12] As stated in Rule 4703(a)(1), an IOC Order is one that is designated to deactivate immediately after determining whether the Order is marketable. Except as provided in Rule 4702 with respect to Opening Cross/Market Hours Orders and Closing Cross/Extended Hours Orders, MOO, LOO, OIO, MOC, LOC and OI Orders all have a Time in Force of IOC, because they are designated for execution in the Nasdaq Opening Cross or the Nasdaq Closing Cross, as applicable, and are cancelled after determining whether they are executable in such cross. Such an Order may also be referred to as having a Time-in-Force of ''On Open'' or ''On Close'', respectively. An MOO, LOO, OIO, MOC, LOC or IO Order, or any other Order with a Time-in-Force of IOC entered between 9:30 a.m. ET and 4:00 p.m. ET, may be referred to as having a Time-in-Force of ''Market Hours Immediate or Cancel'' or ''MIOC.''

prioritization bucket would be as follows, at a new Rule 4752(d)(3)(B):

Displayed Orders, with price as the primary priority, and then within each price level, with time as the secondary priority, including the following: LOOs; OIOs; Limit Orders; the Displayed size of Reserve Orders; other Displayed interests and all Orders with TIFs designated to execute in the Opening Cross and not immediately rebook, unaltered, into the continuous market;

The Exchange proposes to restate and renumber current Rule 4752(d)(3)(D), which prioritizes the execution of the reserve interest of quotes, SDAY limit orders, SGTC limit orders, GTMC limit orders, and SHEX limit orders, at the Nasdaq Opening Cross price with time as the secondary priority. Nasdaq proposes to amend this provision to state expressly what this provision implies—that it encompasses the prioritization of Non-Displayed Orders in price-time priority. Thus, the Exchange proposes to replace Rule 4752(d)(3)(D) with a new Rule 4752(d)(3)(C), which would state as follows: ''Non-Displayed Orders, including LOOs, Limit Orders, and the Non-Displayed size of Reserve Orders, with price as the primary priority, and then within each price level, time as the secondary priority.''

The Exchange proposes to move the last sentence of Rule 4752(d)(3)(B), which states that an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book in Early Market Hours, and which has been deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order, shall be ranked in time priority behind all orders at the price at which the Order was posted to the Nasdaq Book. The Exchange proposes to move this provision to a new, unnumbered paragraph in Rule 4752(d)(3) that follows the prioritization provisions at (d)(3)(A)–(C). This Exchange proposes this change because this provision is not part of the general prioritization of Displayed and Non-Displayed Orders in the Cross; rather it provides for special prioritization of an Order in a specific circumstance involving interaction with a specific Order Type. The Exchange believes that relocating this provision will avoid confusion.

The Exchange proposes to make similar amendments to Rule 4754(b)(3), which governs the execution priority of Orders and interest in the Nasdaq Closing Cross when fewer than all MOC, Limit on Close Orders (''LOCs''),[13] IO, and Close Eligible Interest[14] would be executed therein. Similar to the Opening Cross Rules, the Exchange proposes to retain current Rule 4754(b)(3)(A), which prioritizes execution of Market on Close Orders (''MOCs''),[15] with time as the secondary priority. And again, the Exchange proposes to consolidate and restate the second and third prioritization buckets.

Existing Rule 4754(b)(3)(B) prioritizes LOC, limit orders, Imbalance Only Orders (''IOs''),[16] Displayed quotes and reserve interest priced more aggressively than the Nasdaq Closing Cross price based on price with time as the secondary priority. Meanwhile, existing Rule 4754(b)(3)(C) prioritizes LOCs, IOs, displayed interest of limit orders, and displayed interest of quotes at the Nasdaq Closing Cross price with time as the secondary priority. Again, Nasdaq proposes to consolidate these two buckets into one to state more simply the concept that, in the Closing Cross, the Exchange will prioritize as a group the execution of Displayed Orders and interest, with price as the primary priority, and then within each price level, with time as the secondary priority. As with the Opening Cross, there is no reason to distinguish in the Closing Cross between Orders priced more aggressively than the Closing Cross Price from those priced at the Closing Cross Price, as the concept of price-time priority sufficiently implies that the former category of Orders will execute prior to the latter category of Orders.[17] The proposed amended Rule text also makes clear that all of the Orders in this new single prioritization bucket are either Displayed Orders or are currently treated like Displayed Orders for purposes of execution priority, despite being neither Displayed nor Non-Displayed.[18] This includes auction-only IOC Orders that do not rest on the Book after entry (and thus are neither Displayed nor Non-Displayed, strictly speaking), and are designated to either execute in the Closing Cross or cancel, without rebooking unaltered into the continuous market afterwards. (IOs are another example of such an auction-only Order that is assigned a TIF of IOC and is therefore treated as a Displayed Order for purposes of priority.) The existing prioritization language does not clearly account for such Orders, and the proposal codifies their treatment. The proposed consolidated and restated prioritization bucket would be as follows, at a new Rule 4754(b)(3)(B):

Displayed Orders, with price as the primary priority, and then within each price level, with time as the secondary priority, including the following: LOCs; IOs; Limit orders; the Displayed size of Reserve Orders; other Displayed interest; and all Orders with TIFs designated to execute in the Nasdaq Closing Cross and not immediately rebook, unaltered, into the continuous market after Regular Market Hours;

The Exchange proposes to restate and renumber current Rule 4754(b)(3)(D), which prioritizes the execution of reserve interest at the Nasdaq Closing Cross price with time as the secondary priority. Nasdaq proposes to amend this provision to state expressly what the Exchange intends for this provision to imply—that it encompasses the prioritization of the Non-Displayed portion of Reserve Orders and other Non-Displayed Orders in price-time priority. Thus, the Exchange proposes to replace Rule 4754(b)(3)(D) with a new Rule 4752(b)(3)(C), which would state as follows: ''Non-Displayed Orders, including LOCs, Limit Orders, and the Non-Displayed size of Reserve Orders, with price as the primary priority, and then within each price level, time as the secondary priority.''

The Exchange proposes to delete current Rule 4754(b)(3)(E), which states that unexecuted MOC, LOC, and IO orders will be canceled. The Exchange

[13] A LOC is an Order Type entered with a price that may be executed only in the Nasdaq Closing Cross or the LULD Closing Cross (except as provided herein), and only if the price determined by the Nasdaq Closing Cross or the LULD Closing Cross (except as provided herein) is equal to or better than the price at which the LOC Order was entered. *See* Rule 4702(b)(12).

[14] Close Eligible Interest means any quotation or any order that may be entered into the system and designated with a time-in-force of SDAY, SGTC, MDAY, MGTC, SHEX, or GTMC. *See* Rule 4754(a)(1).

[15] A MOC is an Order Type entered without a price that may be executed only during the Nasdaq Closing Cross at the price determined by the Closing Cross. *See* Rule 4702(b)(11).

[16] An IO is an Order entered with a price that may be executed only in the Nasdaq Closing Cross and only against MOC Orders or LOC Orders. *See* Rule 4702(b)(13).

[17] There is also no reason for the existing Rules to state the different types of Displayed Limit Orders that this bucket contains, as all such Limit Orders are included in it. Thus, the Exchange proposes to refer to these orders collectively as ''Limit Orders.''

[18] The proposed amended Rule also addresses an oversight in the prioritization of Reserve Orders. Currently, Rule 4754(b)(3)(B) expressly sets priority for ''displayed . . . reserve interest''—which refers to the Displayed portion of Reserve Orders—priced more aggressively than the Cross Price. However, Rule 4754(b)(3)(C) does not expressly account for Displayed Reserve interest priced at the Opening Cross Price. Instead, the Rule merely implies that such Orders are included in (C) by referring to ''remaining . . . displayed interest.'' Market participants may find such incongruous language confusing, and the Exchange proposes to delete references to ''reserve interest'' in existing Rule 4754(b)(3)(B) and the ''interest of quotes'' in existing Rule 4754(b)(3)(C) in favor of the phrase ''Displayed size of Reserve Orders.''

proposes to delete this provision because it does not concern the prioritization of execution and it is redundant of statements of the cancellation conductions for these Order Types as set forth in Rule 4702. The Exchange also notes that a similar provision does not exist in Rule 4752(d)(3) governing the Nasdaq Opening Cross, such that the deletion of this provision will render both sets of Cross rules consistent.

The Exchange proposes to move the last sentence of Rule 4754(b)(3)(B), which states that an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book, and which has been deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order, shall be ranked in time priority behind all orders at the price at which the Order was posted to the Nasdaq Book. The Exchange proposes to move this provision to a new, unnumbered paragraph in Rule 4754(b)(3) that follows the prioritization provisions at (b)(3)(A)–(C). This Exchange proposes this change because this provision is not part of the general prioritization of Displayed and Non-Displayed Orders in the Cross; rather it provides for special prioritization of an Order in a specific circumstance involving interaction with a specific Order Type. The Exchange believes that relocating this provision will avoid confusion.

In addition to the above, the Exchange proposes to amend Rule 4753, which governs the Exchange's procedures for conducting the Halt Cross when fewer than all shares of Eligible Interest [19] are executed at the Nasdaq Halt Cross price. Currently, Rule 4753(b)(3) states that, if the Nasdaq Halt Cross price is selected and fewer than all shares of Eligible Interest that are available in the Nasdaq Market Center would be executed, all Eligible Interest shall be executed at the Nasdaq Halt Cross price in price-time priority.[20] The Exchange proposes to amend this Rule to account for the fact that it fails to distinguish between how the System prioritizes Displayed (and IOCs and IOs treated as Displayed Orders) vis-a-vis Non-Displayed Eligible Interest in a Halt Cross. Specifically, the Exchange proposes to amend the reference to ''price/time'' priority to state instead ''price/display/time priority.'' The Exchange also proposes to add a sentence which states that Displayed Eligible Interest and Orders with IOC shall be ranked in time priority ahead of Non-Displayed Eligible Interest with the same prices.

This proposed amendment is intended to codify existing practice and to render Halt Cross prioritization procedures roughly consistent with those of the Opening and Closing Crosses.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Act,[21] in general, and furthers the objectives of section 6(b)(5) of the Act,[22] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest.

It is consistent with the Act to for the Exchange to amend its Rules governing its Crosses so that they account for how the System prioritizes certain Orders in certain situations and so that they accurately and clearly distinguish between how the System prioritizes Displayed versus Non-Displayed variants of Orders in the Crosses, as well as Orders with IOC that do not survive the Crosses. It is in the best interests of investors and the public, and consistent with the maintenance of an orderly market, to maintain comprehensive, accurate, and specific rules governing the prioritization of order execution in the Nasdaq Crosses. Doing so will avoid potential participant and investor confusion and frustration as well as promote confidence and participation in the Crosses.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change will clarify and correct the Exchange's Rules governing its prioritization of order executions in the Cross. Such changes are neither intended to nor will they adversely impact competition. If anything, the Exchange expects that the proposed changes will promote competition by increasing confidence in and the attractiveness of participating in the Exchange's Crosses.

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

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [23] and Rule 19b–4(f)(6) thereunder.[24]

A proposed rule change filed under Rule 19b–4(f)(6) [25] normally does not become operative prior to 30 days after the date of the filing. However, Rule 19b–4(f)(6)(iii) [26] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposed rule change does not raise any new or novel issues. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change as operative upon filing.[27]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such

[19] Eligible Interest is any quotation or any Order that has been entered into the system and designated with a TIF that would allow the order to be in force at the time of the Halt Cross. *See* Rule 4753(a)(5).

[20] Rule 4753(b)(3) also states that an Order to buy (sell) that is locked or crossed at its non-displayed price by a Post-Only Order on the Nasdaq Book, and which has been deemed to have a price at one minimum price increment below (above) the price of the Post-Only Order, shall be ranked in time priority ahead of all orders one minimum price increment below (above) the price of the Post-Only Order but behind all orders at the price at which the Order was posted to the Nasdaq Book.

[21] 15 U.S.C. 78f(b).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78s(b)(3)(A).

[24] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[25] 17 CFR 240.19b–4(f)(6).

[26] 17 CFR 240.19b–4(f)(6)(iii).

[27] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NASDAQ–2023–024 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–NASDAQ–2023–024. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection.

All submissions should refer to file number SR–NASDAQ–2023–024 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16124 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97983; File No. SR–CboeBZX–2023–050]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rules To Provide Users With a Risk Setting They May Elect To Apply to Their Orders That Will Allow Them To Reject Market Orders During Continuous Trading and/or Auctions

July 25, 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 July 14, 2023, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (''BZX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposal to amend Interpretation and Policy .01 to Rule 11.13 in connection with a risk setting that Users[3] may elect to apply to their orders that will allow them to reject market orders during continuous trading and/or auctions.[4] The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/bzx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend Interpretation and Policy .01 to Rule 11.13 to allow the Exchange to offer its Users the ability to apply a risk setting to their orders that will allow them to reject market orders during continuous trading or auctions (''Market Order Check''). Pursuant to Interpretation and Policy .01 to Rule 11.13, the Exchange currently offers certain optional risk settings applicable to a User's activities on the Exchange. Specifically, pursuant to Interpretation and Policy .01(c), the Exchange currently provides Users with the controls to restrict order types or modifiers that can be utilized (including pre-market, post-market, short sales, ISOs, and Directed ISOs). When utilized, this optional risk tool acts as a risk filter by evaluating a User's orders to determine whether the orders comply with certain criteria established by the User.

Based on feedback from its Members, the Exchange now seeks to expand this risk setting to allow a User to restrict additional order types from being entered—market orders during continuous trading and/or market orders during auctions (''Market Order Check'').[5] The Market Order Check will

---

[28] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.13. *See* Rule 1.5(cc).

[4] The Exchange plans to implement the proposed rule change on a date that will be circulated in a notice from the Cboe Trade Desk to all Members.

[5] The Exchange notes that the proposed Market Order Check will treat Stop Orders as regular market orders. A ''Stop Order'' Stop Order is an order that becomes a BZX market order when the stop price is elected. A Stop Order to buy is elected when the consolidated last sale in the security

reside at a User's port level, a User-specific logical session used to access the Exchange. A User may utilize the Market Order Check to control the acceptance of, or rejection of, its inbound market orders. Similarly, a Sponsoring Member[6] may utilize the check to control the acceptance of, or rejection of, its Sponsored Participants[7] inbound market orders. Specifically, when utilized the Market Order Check will allow a User to (1) permit market orders; (2) reject market orders during continuous trading and allow market orders during auctions, or (3) reject market orders during continuous trading and also during auctions. In the case of Sponsored Participants, the Sponsoring Member will be responsible for their Sponsored Participant's Market Order Check settings. The Market Order Check will apply only to equities orders and will not apply to market on open or market on close orders. The proposed Market Order Check is similar in nature to the Order Type/Attribution check offered by Nasdaq Stock Exchange, LLC (''Nasdaq''), which prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders.[8] While the proposed Market Order Check differs slightly from that offered by Nasdaq in that it includes functionality that prohibits the entry of both auction and non-auction market orders, the intended purpose of the control—a risk management tool designed to prevent the entry of orders that may cause undue market impact—remains the same.

Importantly, as is the case with the existing risk settings, the User, and not the Exchange, will have the full responsibility for ensuring that their orders comply with applicable securities rules, laws, and regulations. Furthermore, the Exchange does not believe that the use of the Market Order Check can replace User-managed risk management solutions, and use of the Market Order Check does not automatically constitute compliance with Exchange rules.

The Exchange proposes to make the risk setting available to its Users upon request and will not require Users to utilize the Market Order Check. The Exchange will not provide preferential treatment to Users utilizing the Market Order Check. However, the Exchange believes the Market Order Check will offer Exchange Users another option in efficient risk management of its access to the Exchange. For instance, the Market Order Check may assist some Users in mitigating the risk of receiving executions at unfavorable prices due to market fluctuations and/or available liquidity in the subject security. Similarly, the Market Order Risk Check may serve as a supplemental tool for Sponsoring Members to ensure that market orders entered by their Sponsored Participants do not unexpectedly cause undue impact to the market for a security, which may occur when the market fluctuates, and an order executes at prices significantly different from the price of the security at the time of order entry.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the proposed Market Order Check is designed to protect investors and the public interest because it will provide Users with a tool to help prevent the entry of market orders that may cause unintentional market impact, and reduce the potential for disruptive, market-wide events. The proposed Market Order Check may also assist Users in managing their financial exposure by preventing executions at unfavorable prices, thereby fostering the integrity of trading on the securities markets and helping to assure the stability of the financial system. Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Users because like each of the other Exchange's risk settings, use of the Market Order Check is optional and available to all Users, and its use is not a perquisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed Market Order Check will foster competition because it would allow the Exchange to offer a risk check that is similar to functionality being offered by Nasdaq,[11] which offers an order type/attribution check that prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-

occurs at, or above, the specified stop price. A Stop Order to sell is elected when the consolidated last sale in the security occurs at, or below, the specified stop price. *See* Rule 11.9(c)(16), definition of ''Stop Order''. Separately, the proposed Market Order Check will treat market orders with a ROOC routing option as auction orders. As such, if a User opts to block market orders in continuous trading but allow market orders in auctions, then all market orders with a ROOC routing option will be accepted. If a User chooses to block market orders during both continuous trading and during auctions, then the Market Order Check will prohibit the entry of market orders with a ROOC routing option. The Exchange is describing how it is handling market orders with a ROOC routing option to ensure that Users have a clear understanding of how the Market Order Check will operate in these scenarios. Orders with ROOC routing options are hybrid in nature and can execute in auctions or during continuous trading. As such, an order may fully execute in the auction, as well as receive no execution or receive a partial fill with the remaining shares being posted to the Exchange Book, executed on the Exchange, or routed to other destinations. Given the various iterations that a market order with a ROOC routing option may encounter, the Exchange believes much operational complexity can be avoided by treating market orders with ROOC routing options in this simplified manner. *See* Rule 11.13(b)(3)(N), where the term ''ROOC'' is defined as ''a routing option for orders that the entering firm wishes to designate for the participation in the opening, re-opening (following a halt, suspension, or pause), or closing process of a primary listing market (Cboe BZX, NYSE, Nasdaq, NYSE America, or NYSE Arca) if received before the opening/re-opening/closing time of such market. If shares remain unexecuted after attempting to execute in the opening, reopening, or closing process, they are either posted to the EDGX Book, executed, or routed to destinations on the System routing table.''

[6] The term ''Sponsoring Member'' shall mean a broker-dealer that has been issued a membership by the Exchange who has been designated by a Sponsored Participant to execute, clear and settle transactions resulting from the System. The Sponsoring Member shall be either (i) a clearing firm with membership in a clearing agency registered with the Commission that maintains facilities through which transactions may be cleared or (ii) a correspondent firm with a clearing arrangement with any such clearing firm. *See* Rule 1.5(y), definition of, ''Sponsoring Member''.

[7] The term ''Sponsored Participant'' shall mean a person which has entered into a sponsorship arrangement with a Sponsoring Member pursuant to Rule 11.3. *See* Rule 1.5(x), definition of, ''Sponsored Participant''.

[8] *See* Nasdaq Equity 6, Section 5. Risk Settings (b), ''Order Type/Attribution Check—This control relates to the order types or modifiers that can be utilized (including pre-market, post-market, short sales, non-auction market orders and Intermarket Sweep Orders)'', available at: *https://listingcenter.nasdaq.com/rulebook/Nasdaq/rules/Nasdaq%20Equity%206/market%20impact%20check/EQUALS/#position; see also* Securities Exchange Act Release No. 34–95495 (August 12, 2022), 87 FR 50902 (August 18, 2022) (SR–NASDAQ–2022–047) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Nasdaq Equity 6, Section 5).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 10.

auction market orders. Additionally, by providing Users with additional means to monitor and control their risk, the proposed Market Order Check may enhance proper functioning of the markets and contribute to additional competition among trading venues and broker-dealer dealers. Finally, the proposed Market Order Check will enable Users to strengthen their risk management capabilities, which, in turn, may enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposal. No written comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (A) significantly affect the protection of investors or the public interest; (B) impose any significant burden on competition; and (C) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) [13] thereunder.

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investor and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the 30-day operative delay will allow the Exchange to immediately offer its Users an additional means to mitigate unintended market impact, thus fostering the protection of investors and the public interest. Because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2023–050 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2023–050. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2023–050 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16108 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97984; File No. SR–MSRB–2023–05]

Self-Regulatory Organizations; Municipal Securities Rulemaking Board; Notice of Filing of a Proposed Rule Change To Amend MSRB Rule G–3 To Create an Exemption for Municipal Advisor Representatives From Requalification by Examination and Remove Waiver Provisions and To Amend MSRB Rule G–8 To Establish Related Books and Records Requirements

July 25, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 21, 2023, the Municipal Securities Rulemaking Board (''MSRB'' or ''Board'') 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 the MSRB. The Commission is publishing this notice to

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The MSRB filed with the Commission a proposed rule change to amend MSRB Rule G–3, on professional qualification requirements to (i) remove the waiver provisions with respect to municipal advisor representative and principal qualification requirements; (ii) establish a new, criteria-based exemption to permit certain individuals to requalify as a municipal advisor representative [3] without reexamination; (iii) retitle and replace Supplementary Material .02, on extraordinary waivers with text specifying the means for electronic delivery of the requisite notice to the MSRB regarding satisfaction of the criteria-based exemption; and (iv) make technical changes to the rule to update certain phrases and clauses. The MSRB also proposes to amend MSRB Rule G–8, on books and records, to establish accompanying recordkeeping requirements (the proposed amendments to Rules G–3 and G–8 collectively make up the ''proposed rule change''). The MSRB requests that the proposed rule change be approved with a compliance date of no more than 30 days following the Commission approval date. The proposed rule change is specific to the professional qualification obligations of municipal advisors, including associated persons thereof, under Rule G–3, and does not modify any requirements to firms registered solely as brokers, dealers and/or municipal securities dealers (collectively, ''dealers'' and each, individually ''a dealer''), or associated persons thereof.

The text of the proposed rule change is available on the MSRB's website at *https://msrb.org/2023-SEC-Filings,* at the MSRB's principal office, and at the Commission's Public Reference Room.

[3] Rule G–3(d)(i)(A) defines the term ''municipal advisor representative'' to mean a natural person associated with a municipal advisor who engages in municipal advisory activities, on the municipal advisor's behalf, other than a person performing only clerical, administrative, support or similar functions. Rule G–3(d)(ii)(A) requires all persons meeting the definition of a municipal advisor representative to be qualified in that capacity by taking and passing the Municipal Advisor Representative Qualification Examination (''Series 50 examination'') prior to being qualified as a municipal advisor representative. Under current Rule G–3(d)(ii)(B), any person who, after qualifying as a municipal advisor representative, ceases to be associated with a municipal advisor firm for two or more years shall re-take and pass the Series 50 examination, unless a waiver is granted from the Board in ''extraordinary cases'' pursuant to current Rule G–3(h)(ii).

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 MSRB 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 MSRB 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 MSRB is charged with setting professional qualification standards for dealers and municipal advisors. Specifically, Section 15B(b)(2)(A) of the Act authorizes the MSRB to prescribe standards of training, experience, competence, and such other qualifications as the Board finds necessary or appropriate in the public interest or for the protection of investors and municipal entities or obligated persons.[4] Sections 15B(b)(2)(A)(i) [5] and 15B(b)(2)(A)(iii) [6] of the Act also provide that the Board may appropriately classify associated persons of dealers and municipal advisors and require persons in any such class to pass tests prescribed by the Board. Accordingly, over the years, the MSRB has adopted professional qualification standards to ensure that associated persons of dealers and municipal advisors attain and maintain specified levels of competence and knowledge for each qualification category.

Description of the Proposed Rule Change

As part of the MSRB's rule book modernization initiative and in light of the industry-wide continuing education (CE) transformation initiative for broker-dealers,[7] the MSRB undertook a review of Rule G–3 to identify opportunities to provide individuals associated with municipal advisor firms increased regulatory flexibility with respect to maintaining their professional qualifications. To that end, the proposed rule change would create a one-time, criteria-based exemption, under Rule G–3, for former municipal advisor representatives to, without reexamination, requalify in that capacity no later than one year after their two-year lapse in qualification. Second, the proposed rule change would remove language from Rule G–3 that currently permits the Board, in extraordinary cases, to waive the reexamination requirements for municipal advisor representatives and principals. Third, the proposed rule change would make certain clarifying amendments to Rule G–3 to address an interpretive question pertaining to a lapse in qualification for an individual associated with a dually registered firm that is both a dealer and a municipal advisor. Fourth, the proposed rule change would retitle and replace the current text of Supplementary Material .02 of Rule G–3 with text specifying the means for electronic delivery of the requisite notice to the MSRB regarding satisfaction of the criteria-based exemption. Additionally, the proposed rule change would make technical amendments to Rule G–3 to update certain phrases, clauses and referenced provisions to, among other things, improve the overall readability of the rule. Finally, the proposed rule change would amend Rule G–8 to require municipal advisors to make and keep certain books and records relating to the exemption to be created under the proposed rule change, as prescribed under Rule G–3(h)(ii)(I).

A more detailed description of the proposed rule change follows.

Clarifying Amendments to Rule G–3(d)(ii)(B)

Currently, pursuant to Rule G–3(d)(ii)(B), on qualification requirements for municipal advisor representatives, any person who ceases to be associated with a municipal advisor [8] for two or more years after having qualified as a municipal advisor representative, in accordance with the rule, must take and pass the Series 50 examination prior to being qualified as a municipal advisor representative, unless a waiver is granted. Proposed amendments to this provision would provide that any person who ceases to be associated with

[4] *See* 15 U.S.C. 78*o*–4(b)(2)(A).

[5] *See* 15 U.S.C. 78*o*–4(b)(2)(A)(i).

[6] *See* 15 U.S.C. 78*o*–4(b)(2)(A)(iii).

[7] As industry and market practices evolved in recent years, the MSRB, in coordination with other self-regulatory organizations, advanced rulemaking initiatives to modernize applicable professional qualification and continuing education program requirements for dealers (''CE Transformation''). *See e.g.,* Exchange Act Release No. 95684 (September 7, 2022), 87 FR 56137 (September 13, 2022) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend MSRB Rule G–3 Continuing Education Program Requirements to Harmonize with Industry-Wide Transformation) (File No. SR–MSRB–2022–07).

[8] For purposes of this filing and Exhibit 5, when the term ''municipal advisor'' is used it refers only to the firm and not associated persons of the firm.

''or engaged in municipal advisory activities on behalf of'' a municipal advisor for two or more years after having qualified by examination as a municipal advisor representative (*i.e.,* experiences a ''lapse in qualification'') must take and pass the Series 50 examination unless exempt from such requirement pursuant to Rule G–3(h)(ii), as amended by the proposed rule change.

The proposed amendments to Rule G–3(d)(ii)(B) add the new language ''or engaged in municipal advisory activities on behalf of'' which is intended to provide clarity on the requirement for an individual associated with a firm that is dually registered as a dealer and municipal advisor. If an individual associated with such firm ceases to be engaged in activity requiring qualification as a municipal advisor representative [9] and instead engages only in municipal securities business on behalf of the firm for a period of two or more years, then that individual's municipal advisor representative qualification would have lapsed, notwithstanding the fact that such person remains associated with a firm that is also a registered municipal advisor.[10] The proposed amendments to Rule G–3(d)(ii)(B) would also delete the reference to the mention of a waiver (*i.e.,* the clause ''a waiver is granted'') to clarify that such persons would need to qualify by examination as municipal advisor representatives, unless obtaining the one-time criteria-based exemption.

Relatedly, the proposed rule change would provide a technical amendment to subparagraph (d)(ii)(B) of Rule G–3 by adding the phrase ''lapse in qualification'' to define for purposes of the rule when a person ceases to be associated with a municipal advisor for two or more years at any time after having qualified as a municipal advisor representative. The proposed amendments also would replace the phrase ''a waiver is granted'' with ''exempt'' to make clear that the waiver provision for extraordinary cases is being deleted and replaced with a criteria-based exemption. The technical amendment to change the word ''shall'' to ''must'' is intended to add clarity without changing the meaning of the term. Lastly, the proposed amendments would replace the reference to ''subparagraph'' (h)(ii) with ''paragraph'' (h)(ii) to create better uniformity across Rule G–3.

Clarifying Amendments to Rule G–3(e)(ii)(A) and (B)

Currently, pursuant to Rule G–3(e)(ii)(A), on qualification requirements for municipal advisor principals, as a pre-requisite to becoming qualified as a municipal advisor principal a person must take and pass the Series 50 examination. The proposed amendments to this provision would provide that taking and passing the Series 50 examination is the pre-requisite to becoming qualified as a municipal advisor principal ''unless exempt from taking the Municipal Advisor Representative Qualification Examination pursuant to paragraph (h)(ii) of this rule.'' The proposed amendments to Rule G–3(e)(ii)(A) add the new language ''unless exempt from taking the Municipal Advisor Representative Qualification Examination pursuant to paragraph (h)(ii) of this rule,'' which is intended to allow for individuals previously qualified as municipal advisor principals to use the criteria-based exemption to obtain requalification with the Series 50 examination and provide clarity as to the application to such individuals. Notwithstanding the availability of the criteria-based exemption from requalification with the Series 50 examination, such municipal advisor principals would still need to take and pass the Municipal Advisor Principal Qualification Examination (''Series 54 examination'').

In addition, currently, pursuant to Rule G–3(e)(ii)(B), any person who ceases to be associated with a municipal advisor for two or more years after having qualified as a municipal advisor principal, in accordance with the rule, must take and pass the Series 50 examination and the Series 54 examination prior to being qualified as a municipal advisor principal, unless a waiver is granted under current subparagraph (h)(ii) of this rule. Proposed amendments to this provision would provide that any person who ceases to be associated with ''or engaged in municipal advisory activities on behalf of'' a municipal advisor for two or more years after having qualified by examination as a municipal advisor principal must take and pass the Series 50 examination unless exempt from such requirement pursuant to Rule G–3(h)(ii), as amended by the proposed rule change.

The proposed amendments to Rule G–3(e)(ii)(B) adds the new language ''or engaged in municipal advisory activities on behalf of,'' which is intended to provide clarity on the requirement for an individual associated with a firm that is dually registered as a dealer and municipal advisor. For example, if an individual associated with such firm ceases to be engaged in activity requiring qualification as a municipal advisor principal and instead engages only in municipal securities business on behalf of the firm for a period of two or more years, then that individual's municipal advisor representative and municipal advisor principal qualifications would have lapsed, notwithstanding the fact that such person remains associated with a firm that is also a registered municipal advisor. The proposed amendments to Rule G–3(e)(ii)(B) would also delete the reference to the mention of a waiver (*i.e.,* the clause ''a waiver is granted'') to clarify that such persons would need to qualify by examination as municipal advisor principals.

Relatedly, proposed amendments to Rule G–3 would contain technical amendments to Rules G–3(e)(ii)(A)(1) and G–3(e)(ii)(B). To clarify the qualification requirements specific to municipal advisor principals, as prescribed under G–3(e)(ii)(A)(1), the proposed rule change would add the phrase ''unless exempt from taking the Municipal Advisor Representative Qualification Examination pursuant to paragraph (h)(ii) of this rule'' to make clear municipal advisor principals have to requalify by reexamination unless such individuals have obtained the one-time exemption. The proposed rule change would delete the phrase ''a waiver is granted'' and replace with the clause ''exempt from taking the Municipal Advisor Representative Qualification Examination'' to make clear that the waiver provision for extraordinary cases is being deleted and replaced with an exemption-based criteria for municipal advisor principals to use for requalification without reexamination for the Series 50 examination. Similarly, as previously mentioned, the word ''shall'' would be replaced with ''must'' to promote

[9] Pursuant to Section 15B(e)(4)(A)(i) and (ii) of the Act (15 U.S.C. 78*o*–4(e)(4)(A)(i) and (ii)) and Rules D–13, G–3(d)(i)(A), and G–3(d)(ii)(A), municipal advisory activities requiring qualification as a municipal advisor representative include providing advice to or on behalf of a municipal entity or obligated person with respect to municipal financial products or the issuance of municipal securities, including advice with respect to the structure, timing, terms, and other similar matters concerning such financial products or issues; or undertaking a solicitation of a municipal entity or obligated person.

[10] Under Exchange Act Rule 15Ba1–2, SEC Form MA–I: Information Regarding Natural Persons Who Engage in Municipal Advisory Activities (''SEC Form MA–I'') is filed with the SEC to indicate natural persons who are associated with the municipal advisor and engaged in municipal advisory activities on its behalf. *See* 17 CFR 240.15Ba1–2. Firms are required to promptly amend Form MA–I, pursuant to Exchange Act Rule 15Ba1–5 (17 CFR 240.15Ba1–5), in such cases where an individual ceases to engage in municipal advisory activities on behalf of a firm.

clarity; and proposed amendments would replace the reference to ''subparagraph'' (h)(ii) with ''paragraph'' (h)(ii) to create better uniformity across Rule G–3.

Removal of Extraordinary Waiver Provisions Under Rule G–3(h)(ii)

Proposed amendments to Rule G–3(h)(ii) would remove references, in their entirety, to the ability to obtain a waiver in extraordinary cases for a former municipal advisor representative or municipal advisor principal and would replace such language with a criteria-based exemption for former municipal advisor representatives. The MSRB believes that this standard set forth within the four corners of the rule would provide greater flexibility to municipal advisor firms and their associated persons while simultaneously providing greater certainty for firms and such individuals who may wish to seek an exemption from the obligation to requalify as a municipal advisor representative by reexamination. At this time, the MSRB believes that the objective nature of the criteria-based exemption is preferable to the subjective nature of the waiver provisions in current Rule G–3(h)(ii). Additionally, the removal of the ability to seek and obtain a waiver for municipal advisor principals furthers municipal entity and obligated person protection by ensuring, through requalification by reexamination, individuals have demonstrated knowledge and skills necessary to discharge the responsibilities of a municipal advisor principal, including the vested authority for the supervision, oversight and management of firms' municipal advisory activities and that of its associated persons.[11]

Relatedly, proposed amendments to Supplementary Material .02, on waivers, under Rule G–3 would retitle that paragraph to ''affirmation notification'' and delete the entirety of that supplementary material, which currently pertains to extraordinary waivers, and would replace it with text that specifies how notice regarding use of the criteria-based exemption would be required to be submitted to the MSRB.

The proposed rule change to amend Rule G–3(h)(ii) to establish the criteria-based conditions that would be required to be met in order to qualify for an exemption are described below.

Proposed Rule Change To Adopt Rule G–3(h)(ii)(A)–(I) To Establish Conditions for Obtaining the Criteria-Based Exemption

The proposed rule change would amend Rule G–3(h)(ii) to prescribe that an individual shall be exempt from the requirements of subparagraph (d)(ii)(B) if the specified conditions under proposed Rule G–3(h)(ii)(A)–(I) are met. Specifically, proposed amendments to adopt Rule G–3(h)(ii)(A)–(I) would establish nine specified criteria-based conditions that must be met in order for an individual (and the municipal advisor firm with which such individual is associated[12] or seeks to be associated) to take advantage of the exemption.

The criteria-based conditions that would be required to be met in order to qualify for an exemption are described below.

(1) The individual was previously qualified as a municipal advisor representative by taking and passing the Series 50 examination.

(2) The individual maintained the municipal advisor representative qualification for a period of at least three consecutive years while associated with and engaging in municipal advisory activities on behalf of one or more municipal advisor firm(s).

(3) Such qualification lapsed pursuant to proposed amended Rule G–3(d)(ii)(B) and no more than one year has passed since such lapse in qualification.

(4) The individual has not engaged in activities requiring qualification as a municipal advisor representative[13] during the individual's lapse in qualification.

(5) The individual is not subject to any events or proceedings that resulted in a regulatory action disclosure report, a civil judicial action disclosure report, customer complaint/arbitration/civil litigation disclosure report, criminal action disclosure report or termination disclosure report on SEC Form MA–I.[14]

(6) The individual has not previously obtained the exemption from requalification by examination described in the proposed amended Rule G–3(h)(ii).[15]

(7) Prior to engaging in municipal advisory activities on behalf of the municipal advisor firm with which the individual is to associate (or reassociate), as evidenced by the filing of SEC Form MA–I, the municipal advisor firm provided, and the individual completed, CE covering, at minimum, the subject areas of: (i) the principles of fair dealing; (ii) the applicable regulatory obligations under Rules G–20, on gifts and gratuities, G–37, on political contributions and prohibitions on municipal securities business and municipal advisory business, G–40, on advertising by municipal advisors, and G–8, on books and records to be made and maintained; (iii) for non-solicitor municipal advisors, the core conduct standards under Rule G–42, including the fiduciary duty obligations owed to municipal entity clients, or for solicitor municipal advisors, the core obligations of Rule G–46; and (iv) any changes to applicable securities laws and regulations, including applicable MSRB rules that were adopted since the individual was last associated with a municipal advisor.

(8) Prior to engaging in municipal advisory activities on behalf of the municipal advisor firm with which the individual is to associate (or reassociate), as evidenced by the filing of an SEC Form MA–I, the municipal advisor firm provided, and the individual reviewed the compliance

[11] The MSRB has previously stated that the Series 54 examination is intended to ensure that a person seeking to qualify as a municipal advisor principal satisfies a specified level of competency and knowledge by measuring a candidate's ability to apply the applicable federal securities laws, including MSRB rules to the municipal advisory activities of a municipal advisor. *See* Exchange Act Release No. 84341 (October 2, 2018), 83 FR 50708, 50710 (October 9, 2018) (Notice of Filing of a Proposed Rule Change To Amend MSRB Rule G–3, on Professional Qualification Requirements, To Require Municipal Advisor Principals To Become Appropriately Qualified by Passing the Municipal Advisor Principal Qualification Examination) (File No. SR–MSRB–2018–07). In contrast, the MSRB has previously noted that the Series 50 examination ensures a minimum level of knowledge of the job responsibilities and regulatory requirements by passing the general qualification examination. *See* Exchange Act Release No. 73708 (December 1, 2014), 79 FR 72225, 72227 (December 5, 2014) (Notice of Filing of a Proposed Rule Change Consisting of Proposed Amendments to MSRB Rules G–1, on Separately Identifiable Department or Division of a Bank; G–2, on Standards of Professional Qualification; G–3, on Professional Qualification Requirements; and D–13, on Municipal Advisory Activities) (File No. SR–MSRB–2014–08).

[12] The MSRB notes that an individual who has associated with a municipal advisor firm may not engage in any municipal advisory activities, as defined under Rule D–13 and described in Section 15B(e)(4)(A)(i) and (ii) of the Act (15 U.S.C. 78*o*–4(e)(4)(A)(i) and (ii)) and the rules and regulations promulgated thereunder (*i.e.,* activities involving the provision of advice to or on behalf of a municipal entity or obligated person with respect to municipal financial products or the issuance of municipal securities or undertaking a solicitation of a municipal entity or obligated person), until such time that the individual has satisfied the conditions set forth under the rule.

[13] *See* Rule G–3(d)(i)(A).

[14] The MSRB included these types of disclosures in the exemption criteria, as opposed to other types of disclosures required by SEC Form MA–I, because these relate most closely to violations of municipal advisor-related or investment-related regulations, rules, or industry standards of conduct.

[15] Should an individual's municipal advisor representative qualification lapse again after such person obtains the criteria-based exemption, that individual would be required to requalify by taking and passing the Series 50 examination.

policies and procedures of the municipal advisor firm.

(9) Upon satisfaction of the conditions set forth in the paragraphs above, the municipal advisor firm filed a completed SEC Form MA–I with the SEC with respect to such individual. Within 30 days of the acceptance [16] of a completed SEC Form MA–I identifying such individual as engaging in municipal advisory activities on behalf of the municipal advisor firm, the municipal advisor firm provided the notification (''affirmation notification'') electronically to the MSRB that the individual met the criteria in order to be exempt from the requalification requirements of Rule G–3(d)(ii)(B) following a lapse in qualification.

The affirmation notification would be required to be on firm letterhead and include the following information:

1. The municipal advisor firm's MSRB ID number;
2. The first and last name of the individual seeking to obtain the exemption;
3. The individual's FINRA Central Registration Depository (CRD) number if applicable;
4. The start date of the individual's association (or reassociation) with the municipal advisor firm;
5. An affirmative statement that the municipal advisor has undertaken a diligent effort to reasonably conclude that the individual met the applicable requirements set forth in proposed amended Rule G–3(h)(ii);
6. An affirmative statement attesting that the municipal advisor firm provided both the requisite CE and the municipal advisor's compliance policies and procedures to the individual for review along with the date the individual completed the CE and review of the municipal advisor's compliance policies and procedures provided by the municipal advisor firm;
7. The date the municipal advisor firm filed SEC Form MA–I (and the date of its acceptance) on behalf of the individual as required under subparagraph (h)(ii)(I); and
8. A signature by the individual seeking to obtain the criteria-based exemption and a signature by a municipal advisor principal of the municipal advisor firm each attesting the accuracy of certain content set forth in the affirmation notification. Specifically, the individual must sign the affirmation notification attesting that the conditions outlined in proposed amended Rule G–3(h)(ii)(A) through (H) were met. And, a municipal advisor principal must sign the affirmation notification, on behalf of the municipal advisor firm, attesting that, based on the exercise of reasonable diligence, the conditions outlined in proposed amended Rule G–3(h)(ii)(A) through (I) were met.[17]

Additionally, the affirmation notification required to be provided to the MSRB within 30 days of the acceptance of a completed SEC Form MA–I, pursuant to subparagraph (h)(ii)(I) of this rule would be required to be sent to *Compliance@msrb.org,* in accordance with proposed amended Supplementary Material .02 of Rule G–3.

The conditions are designed to ensure that individuals seeking to obtain the exemption (*i.e.,* requalification without reexamination) have and maintain the baseline level of knowledge and experience, and have exhibited conduct aligned with being a fiduciary, which is in furtherance of municipal entity and obligated person protection. The MSRB believes that the criteria outlined above balance the goal of providing reasonable regulatory flexibility with the demands of the fiduciary standard applicable to municipal advisors. For example, the requirement that individuals were duly qualified as a municipal advisor representative for at least three consecutive years prior to, for example, seeking other career opportunities in related capacities (*i.e.,* working for a dealer or municipal entity) or stepping away for family obligations ensures that a reasonable level of professional experience has been established before an individual can obtain the exemption. In contrast, this period is not so long as to hinder the ability, at a given point, for an individual to, for example, temporarily engage in other meaningful roles within the municipal securities industry or to step away due to family obligations.

At the same time, these conditions are designed to enhance an individual's familiarity with regulatory and business developments that occurred while they were not associated with a municipal advisor firm, before reengaging in municipal advisory activities, but are not so unduly burdensome as to hinder reassociation. The requirement to provide the MSRB with notice of individuals who have obtained the exemption (*i.e.,* by submitting the affirmation notification to the MSRB) is designed to facilitate transparency and provide an audit trail regarding an individual's status as a municipal advisor representative. The MSRB will use the affirmation notification, as described in the proposed amended Rule G–3(h)(ii)(I), to help identify qualified municipal advisor representatives and keep the list of such representatives updated on the MSRB's website.[18] Additionally, the conditions pertaining to requisite filings with the SEC also provide an audit trail and permit the entities charged with examination and enforcement authority to confirm compliance with relevant obligations.

Relatedly, technical amendments to Rule G–3(h) would retitle the header from ''Waiver of Qualification Requirements'' to ''Waiver of and Exemption from Qualification Requirements'' to promote clarity. Technical amendments to Rule G–3(h)(ii) replace the introductory sentence ''The requirements of paragraph (d)(ii)(A) and (e)(ii)(A) may be waived by the Board in extraordinary cases for a municipal advisor representative or municipal advisor principal'' with the new introductory sentence ''An individual shall be exempt from the requirements of subparagraph (d)(ii)(B) if all of the following conditions are met'' for purposes of setting forth the enumerated criteria outlined under the provision.

Finally, as previously mentioned, the proposed amendments to Supplementary Material .02, on waivers, under Rule G–3 would retitle the paragraph header from ''Waivers'' to ''Affirmation Notification'' and delete the entirety of that supplementary material, which currently pertains to extraordinary waivers, and would replace it with text that specifies how the firm would submit to the MSRB the affirmation notification asserting that the criteria-based exemption has been met.

Timing for Completing the Requisite CE, Review of Compliance Policies and Procedures, and Making the Requisite Form Filings

The MSRB has consistently stated that individuals should take and pass the Series 50 examination before completing the necessary form filings to become associated persons of municipal

[16] The SEC does not make the form acceptance date publicly available, but this information is made available to the form submitter as part of the form filing process.

[17] The MSRB notes that the respective individual and firm signature requirements are intended to differentiate and confirm the distinct responsibilities and obligations of the individual seeking to obtain the criteria-based exemption and those of the municipal advisor firm itself, as evidenced by the signature of a municipal advisor principal on behalf of the municipal advisor firm.

[18] The MSRB publishes a list of registered municipal advisors and qualified municipal advisor professionals (available at: *https://www.msrb.org/Municipal-Advisors*).

advisor firms or before registering as municipal advisor firms.[19] As a result, an individual associating with a municipal advisor firm and seeking to use the exemption should, in the following order:

(i) take and complete the requisite CE (*e.g.,* resources available through trade associations or the MSRB, firm-developed materials, or off-the-shelf purchased materials);

(ii) review the municipal advisor firm's compliance policies and procedures;

(iii) have the municipal advisor firm complete SEC Form MA–I in accordance with the instructions in the form and file the form electronically with the SEC; and

(iv) submit the requisite affirmation notification to the MSRB within 30 days of the acceptance of a completed SEC Form MA–I.

Whereas, solo-practitioners seeking to use the exemption should in the following order:

(i) take and complete the requisite CE (*e.g.,* resources available through trade associations or the MSRB, firm-developed materials, or off-the-shelf purchased materials);

(ii) review the developed compliance policies and procedures of the municipal advisor firm;

(iii) complete SEC Form MA–I in accordance with the instructions in the form and file the form electronically with the SEC;

(iv) complete SEC Form MA: Application For Municipal Advisor Registration/Annual Update Of Municipal Advisor Registration/ Amendment of A Prior Application For Registration (''SEC Form MA'') in accordance with the instructions in the form and file the form electronically with the SEC;[20]

(v) complete MSRB Form A–12, on registration, in accordance with the instructions outlined in the MSRB Registration Manual[21] and file the form electronically with the MSRB;[22] and

(vi) submit the requisite affirmation notification to the MSRB within 30 days of the acceptance of a completed SEC Form MA–I.

Proposed Amendments Related to G–8, on Books and Records To Be Made and Maintained

Proposed amendments to Rule G–8, on books and records, would add recordkeeping obligations designed to help facilitate and document compliance with proposed amendments to Rule G–3. Specifically, the proposed rule change would add new paragraph (C) to subsection (h)(vii) of Rule G–8 requiring municipal advisor firms to make and maintain the following records to evidence compliance with the requirements of Rule G–3(h)(ii)(A)–(I):

- A record evidencing that the individual seeking to obtain the exemption was previously duly qualified as a municipal advisor representative (*e.g.,* copy of the print-out of the individual exam results[23] or exam result certification letter provided by the MSRB);
- Documentation supporting the municipal advisor firm's exercise of reasonable diligence in determining that the conditions outlined in Rule G–3(h)(ii)(A) through (I) were met in making the required affirmation notification in accordance with Rule G–3(h)(ii)(I)(8) (*e.g.,* copies of relevant SEC form filings reviewed; records related to continuing education provided and completed; compliance policies and procedures provided and reviewed; and attestations or other documentation to support such a determination);
- A copy of the affirmation notification sent to the MSRB as required by Rule G–3(h)(ii)(I); and
- A record evidencing that the affirmation notification was made in the prescribed manner and within the required period of time as described in Rule G–3(h)(ii)(I) (*e.g.,* automatic email delivery receipt).

As aforementioned, the proposed rule change outlining the specific recordkeeping requirements supports the municipal advisor principal's supervision, review and sign-off that the conditions for the exemption have been met, which supports regulatory compliance.

Relatedly, technical amendments to Rule G–8(h)(vii) would retitle the paragraph header from ''Records Concerning Compliance with Continuing Education Requirements'' to ''Records Concerning Compliance with Professional Qualification Requirements of Rule G–3'' to clarify the broader recordkeeping obligations and documentation requirements proposed in draft amendments to Rule G–8(h)(vii) that are accompanying proposed rule changes to Rule G–3(h)(ii). The other technical changes would reposition the word ''and'' and make other minor grammatical changes to the items in the series to aid readability.

2. Statutory Basis

The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(A) of the Act,[24] which authorizes the MSRB to prescribe standards of training, experience, competence, and such other qualifications as the Board finds necessary or appropriate for the protection of municipal entities or obligated persons; and Section 15B(b)(2)(C) of the Act,[25] which provides that the MSRB's rules shall, among other things, be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination among regulators, and, in general, to protect municipal entities, obligated persons, and the public interest.

Under Section 15B(b)(2)(A) of the Act,[26] the proposed rule change is appropriate and in the public interest because more efficient, effective and flexible professional qualification requirements for municipal advisor representatives will lead to a broader applicant pool from which municipal advisor firms may hire. A broader municipal advisor representative applicant pool is in the public interest and will help protect municipal entities or obligated persons because such pool can improve the quality of municipal advisor representative candidates and increase diversity in the industry. By expanding the potential number of municipal advisor representative candidates, a firm may have greater choice in hiring qualified individuals. For example, individuals that may disassociate with a municipal advisor firm may determine to associate with a dealer in a public finance banker capacity or to work for a municipal entity. Such individuals may receive valuable and directly applicable experience from a different vantage point in the industry that would augment their prior and future experience as a municipal advisor

[19] *See* Question 17 of ''FAQs on Municipal Advisor Professional Qualification and Examination Requirements'' (available at: *https://www.msrb.org/sites/default/files/FAQ-MSRB-Series-50-Exam.pdf*).

[20] Filing Form MA and Form MA–I is mandatory for municipal advisor firms that are required to register with the SEC. *See* 17 CFR 240.15Ba1–2(a) and (b).

[21] The MSRB Registration Manual is available at *https://www.msrb.org/sites/default/files/MSRB-Registration-Manual.pdf.*

[22] Pursuant to Rule A–12, on registration, a municipal advisor must register with the MSRB before engaging in municipal advisory activities; prior to their MSRB registration, they must register with the SEC and have such registration approved.

[23] *See* Question 11 of ''FAQs on Municipal Advisor Professional Qualification and Examination Requirements'' (available at: *https://www.msrb.org/sites/default/files/FAQ-MSRB-Series-50-Exam.pdf*) in which the MSRB reminds individuals that the test center will provide a print-out of individuals' exam results.

[24] 15 U.S.C. 78*o*–4(b)(2)(A).

[25] 15 U.S.C. 78*o*–4(b)(2)(C).

[26] 15 U.S.C. 78*o*–4(b)(2)(A).

representative upon reassociating with a municipal advisor firm. This difference in perspective and experience could put such municipal advisor representative candidates in a position to provide more informed advice than they may otherwise have provided.

Similarly, a broader applicant pool increases the likelihood of greater diversity among municipal advisor representatives who can bring new perspectives to their work and the advice that they provide to their municipal entity and obligated person clients. Additionally, by hiring well-qualified candidates, firms can build bench strength and work to leverage institutional knowledge; thereby enhancing the informed advice provided to a municipal advisor firm's municipal entity and obligated person clients.

At the same time, the proposed rule change requires the satisfaction of conditions that establish safeguards and ensure that only qualified candidates may seek to obtain the criteria-based exemption from requalification, thereby furthering municipal entity and obligated person protection and the public interest. Specifically, the stated criteria of at least three years of experience before eligibility for the criteria-based exemption and no more than three years since ceasing to be associated with a municipal advisor firm is in furtherance of municipal entity and obligated person protection because these criteria support individuals maintaining their baseline level of experience and competence. The MSRB believes that the three-year thresholds, as opposed to a longer or shorter period, appropriately support the ability to establish a necessary and meaningful level of proficiency as a municipal advisor representative prior to obtaining the exemption. In contrast, while ensuring that such regulatory flexibility is available for a limited period of time, on a one-time basis, individuals retain the value of that established proficiency and can more readily adapt to changes in market practices or regulatory requirements upon reengaging in a municipal advisor representative capacity.

Prevention of Fraudulent and Manipulative Acts and Practices

In accordance with Section 15B(b)(2)(C) of the Act,[27] the proposed rule change also would continue to prevent fraudulent and manipulative acts and practices by ensuring that municipal advisor representatives meet competence, training, experience and qualification standards, and such protections would not be diminished by the proposed rule change. As noted above, the stated criteria of at least three years of experience before eligibility for the exemption and no more than three years since ceasing to be associated with a municipal advisor firm support individuals in maintaining their baseline level of experience and competence. In addition, the proposed rule change would require individuals seeking to obtain the exemption to, upon associating (or reassociating) with a municipal advisor firm, receive relevant and updated core training pertaining to regulatory obligations under applicable securities laws and regulations, including MSRB rules, which furthers the prevention of manipulative acts and practices. The MSRB believes that the three-year thresholds coupled with the more robust CE training requirements continue to support the establishment of the necessary experience, competence, and training, which in turn serves to help prevent fraudulent and manipulative practices and protect municipal entities, obligated persons, and the public interest.

Protection of Municipal Entities, Obligated Persons, and the Public Interest

Consistent with Section 15B(b)(2)(C) of the Act[28] and the above discussion, the proposed rule change would continue to protect municipal entities, obligated persons and the public interest because municipal advisor representatives would be required to obtain CE pertaining to specified topics and regulatory obligations under applicable securities laws and regulations, including MSRB rules in order to requalify as a municipal advisor professional. Additionally, such individuals would not be able to obtain the criteria-based exemption if they either engaged in activities requiring qualification as a municipal advisor representative during their lapse in qualification or they are subject to any events or proceedings that resulted in a regulatory action disclosure report, a civil judicial action disclosure report, customer complaint/arbitration/civil litigation disclosure report, criminal action disclosure report or terminations disclosure report on the SEC Form MA–I. These conditions help ensure that basic municipal entity and obligated person protections remain in place while also providing municipal advisor representatives flexibility to pursue other meaningful roles within the municipal securities industry or to step away for other reasons; and benefits municipal advisor firms by providing the increased ability to attract qualified talent.

As noted above, a broader municipal advisor representative applicant pool is in the public interest and will help protect municipal entities and obligated persons because it can improve the quality of municipal advisor representative candidates and increase diversity in the municipal advisory industry, all of which could enhance the quality of advice provided to municipal entity and obligated person clients.

Finally, the MSRB believes that the removal of the ability of a municipal advisor representative or principal to apply to the Board and, potentially, receive a waiver from the obligation to requalify by reexamination would further protect municipal entities and obligated persons. As discussed, the proposed rule change would replace such ability with the criteria-based exemption. However, it would not extend such exemption to municipal advisor principals because the MSRB believes principals should be subject to additional regulatory requirements given their supervisory, oversight, and management duties, and the current criteria-based exemption does not contemplate such rigor and heightened regulatory requirements. In practice, the MSRB has not received or granted waiver requests for municipal advisor principals. Requiring all municipal advisor principals to requalify by reexamination following a lapse in qualification ensures municipal entity and obligated person protection by necessitating that municipal advisor principals satisfy a specified level of competency and knowledge of the applicable securities laws and regulations, including MSRB rules, in order to perform their duties.[29]

Fostering Cooperation and Coordination

Proposed amendments to Rule G–8, on books and records, would add specific recordkeeping obligations designed to help facilitate and document compliance with proposed

[27] 15 U.S.C. 78*o*–4(b)(2)(C).

[28] *Id.*

[29] As discussed in the section below regarding burden on competition, current Rule G–3(e)(ii)(C) permits solo-practitioners (or individuals associating or re-associating with a firm and designated as a principal) who are qualified as municipal advisor representatives to function as municipal advisor principals for up to 120 days before having to take and pass the Series 54 examination. In concert with the proposed rule change, these provisions would allow such individuals to start their own firm, requalify as municipal securities representatives without reexamination, and then qualify as municipal advisor principals.

amendments to Rule G–3. Specifically, the proposed amendments would add a new paragraph (C) to subsection (h)(vii) of Rule G–8 that would require municipal advisor firms to make and maintain records to evidence their due diligence to ensure compliance with the criteria-based exemption by individuals seeking to obtain the exemption, and of the affirmation notification provided to the MSRB required by proposed amendments to Rule G–3(h)(ii)(I). The MSRB believes that the proposed rule change is consistent with Section 15B(b)(2)(C) of the Act [30] because the specific documentation obligation and related books and records obligations stemming from the proposed amendments to Rule G–8(h)(vii)(C) would foster cooperation by providing examining authorities with the necessary information to assist them in examining for and evaluating compliance with the criteria-based exemption. The MSRB further believes that the rigor of such review by examining authorities for compliance with the prescribed recordkeeping obligations would foster municipal entity and obligated person protection because municipal advisor firms would take due care to ensure compliance with the qualification standards under the criteria-based exemption and that only such individuals that satisfy such exemption are engaging in municipal advisor activities. Lastly, as aforementioned, the MSRB believes that the proposed amendments to Rule G–8(h)(vii)(C) would help create an audit trail to assist examination and enforcement authorities in their examination for compliance with the criteria-based exemption, fostering cooperation and coordination between regulatory authorities.

Promote Just and Equitable Principles of Trade

The technical amendments outlined throughout are consistent with the provisions of Section 15B(b)(2)(C) of the Act [31] in that they promote just and equitable principles of trade by ensuring that Rules G–3 and G–8 remain accurate, clear and understandable for the municipal advisory community.

B. Self-Regulatory Organization's Statement on Burden on Competition

Section 15B(b)(2)(C) of the Act [32] requires that MSRB rules not be designed to impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Furthermore, Section 15B(b)(2)(L)(iv) of the Act [33] requires that rules adopted by the MSRB not impose a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud. The MSRB does not believe that the proposed amendments to Rule G–3 and Rule G–8 would impose any unnecessary or inappropriate burden or impact on competition, as they would provide additional flexibility and certainty to those seeking to associate with municipal advisor firms as municipal advisor representatives and to municipal advisor firms, thereby, enhancing the hiring of qualified, experienced individuals; and they would also support evidencing compliance with the criteria-based exemption.

In determining whether the standards under Section 15B(b)(2)(C) [34] and (b)(2)(L)(iv) [35] of the Act related to burden on competition and burden on small municipal advisors have been satisfied, the MSRB was guided by the Board's Policy on the Use of Economic Analysis in MSRB Rulemaking.[36] In accordance with this policy, the MSRB has evaluated the potential impacts on competition of the proposed amendments to Rule G–3 and Rule G–8. The proposed amendments to Rule G–3 would create a criteria-based exemption for individuals to requalify in a municipal advisor representative capacity without reexamination after a lapse in qualification. The proposed rule change would remove language from Rule G–3 that currently permits municipal advisor professionals to seek a waiver from the MSRB from the requirement to requalify by reexamination in extraordinary cases. Additionally, the proposed rule change would make accompanying amendments to Rule G–8 to establish books and records requirements related to the criteria-based exemption. The proposed amendments to Rule G–3 and accompanying amendments to Rule G–8 are intended to offer flexibility, provide additional certainty, and eliminate the extraordinary nature of the waiver process for individuals and municipal advisor firms without reducing protection for municipal entity and obligated person clients who expect that municipal advisor professionals have satisfied professional qualification standards. Specifically, proposed amendments to Rule G–3 would afford an individual whose qualification as a municipal advisor representative has lapsed the opportunity to forego requalification by reexamination if certain, specified conditions are met.

Although the proposed amendments to Rule G–3 and Rule G–8 would be applied equally to all individuals seeking to associate with municipal advisor firms and to all such municipal advisor firms, the MSRB acknowledges potential burdens on competition for small or solo-practitioner municipal advisor firms with respect to the exemption's CE requirements and because the exemption does not extend to municipal advisor principals. As a result, although all firms would benefit from the proposed rule change for municipal advisor representatives, solo-practitioners and smaller municipal advisor firms may experience a smaller benefit than larger municipal advisor firms due to the fact the exemption would not extend to those seeking to associate and function in a principal-level capacity. However, as discussed in detail below, the MSRB believes the proposed amendments to Rule G–3 and Rule G–8 would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act [37] or a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud.[38]

Benefits, Costs and Effect on Competition

The main benefit of proposed amendments to Rule G–3 and Rule G–8 would be to create a criteria-based exemption and related recordkeeping requirements. The MSRB considered the economic impact associated with the proposed amendments to Rule G–3 relative to the baseline, which is the current extraordinary waiver provision and assessed incremental changes in the benefits and costs in a proposed future state with a criteria-based exemption for municipal advisor representatives.

[30] 15 U.S.C. 78*o*–4(b)(2)(C).

[31] *Id.*

[32] *Id.*

[33] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

[34] 15 U.S.C. 78*o*–4(b)(2)(C).

[35] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

[36] Policy on the Use of Economic Analysis in MSRB Rulemaking is available at *http://msrb.org/Rules-and-Interpretations/Economic-Analysis-Policy.aspx.* In evaluating whether there was a burden on competition, the Board was guided by its principles that required the Board to consider costs and benefits of a rule change, its impact on capital formation and the main reasonable alternative regulatory approaches.

[37] 15 U.S.C. 78*o*–4(b)(2)(C).

[38] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

The MSRB believes that the proposed rule change provides multiple benefits to the eligible population of individuals seeking to associate with municipal advisor firms as municipal advisor representatives, and municipal advisor firms without impairing the protections afforded to municipal entity and obligated person clients of municipal advisor firms. First, by increasing the amount of time in which an individual may maintain their qualification as a municipal advisor representative without reexamination, the proposed rule change provides flexibility for certain individuals to, for example, explore other career opportunities in the municipal securities industry or to step away to address life events, such as childcare or pursue higher education. As a result, the criteria-based exemption provided by the proposed rule change may increase demand for individuals seeking to reassociate in a municipal advisor representative capacity without having to retake the Series 50 examination.

The proposed rule change would require CE that includes coverage of specific subject areas and regulatory topics, which would ensure the most useful and up-to-date training is provided to individuals who wish to take advantage of the proposed exemption, therefore benefiting municipal entity and obligated person clients who may receive municipal advisory services from the firms with which such persons are associated. Furthermore, the proposed rule change reduces uncertainty for individuals seeking to requalify by providing clarity on the specific criteria needed to requalify without reexamination; and therefore, expedites the period by which such individuals can begin to engage in municipal advisory activities. In addition, municipal advisor firms would be better positioned to assess a potential hire's qualifications by evaluating the conditions specified in the proposed rule change. Finally, while Rule G–3 does not currently require a minimum number of years of past experience to reassociate with a municipal advisor firm within the specified two-year period, the MSRB believes establishing eligibility criterion of at least three consecutive years of past experience to qualify for the criteria-based exemption promotes municipal entity and obligated person protection by ensuring individuals have an established baseline level of knowledge and experience.

The MSRB believes there is the potential for one-time upfront costs for municipal advisor firms related to revising CE training materials and existing compliance policies and procedures to facilitate compliance with the proposed amendments to Rule G–3 and Rule G–8. However, these associated costs should be minor (*see* Table 1). Additionally, under the criteria individuals and municipal advisor firms must meet to obtain the exemption, there may be additional ongoing cost components to firms associated with conducting due diligence when rehiring a previously qualified municipal advisor representative and administering the specified CE required to meet the exemption. The MSRB estimates the aforementioned cost components at approximately four hours incrementally (*see* Table 1), given that some current costs already exist associated with CE and performing due diligence in the baseline state. However, for municipal advisor firms that do not hire an individual with a lapsed qualification, there would be minimal additional costs incurred. Lastly, individuals who are away from the industry for more than three years would be required to take and pass the Series 50 examination again under the proposed rule change, as the waiver request provisions, available only in extraordinary cases, would no longer be available. However, given the limited use of the waiver process currently,[39] the MSRB does not believe the elimination of this option would have a significant impact on individuals seeking to reassociate in a municipal advisor representative capacity.

Table 1. Estimated Incremental Compliance Costs for each Municipal Advisor Firm[40]

Cost Components	Assumed Hourly Rate	Number of Hours	Cost Per Firm
Upfront Cost			
a) Revision of Policies and Procedures	$ 536	3	$ 1,608
b) Training	$ 616	1	$ 616
Ongoing Cost			
a) Due Diligence and Continuing Education	$ 502	4	$ 2,008

[39] To date, the MSRB has received only two waiver requests. The two requests were specific only to waiving the Series 50 examination (*i.e.,* not a Series 54 examination waiver request), with one of the waivers being received following the publication of MSRB Notice 2022–13. *See* MSRB Notice 2022–13 (Request for Comment on Draft Amendments to Create an Exemption for Municipal Advisor Representatives from Requalification by Examination) (''RFC'') (December 1, 2022) (available at: *https://msrb.org/sites/default/files/2022-11/2022-13.pdf*).

[40] The hourly rate data was gathered from the 2013 SEC's Final Rule on Registration of Municipal Advisors. *See* Exchange Act Release No. 70462 (September 20, 2013), 78 FR 67594, 67609 (November 12, 2013) (File No. S7–45–10). The data reflects the 2023 hourly rate level after adjusting for the annual wage inflation rate of 2% between 2013 and 2021. *See The Federal Reserve Bank of St. Louis Employment Cost Index: Wages and Salaries Private Industry* (available at: *https://fred.stlouisfed.org/series/ECIWAG*). The MSRB uses a blended hourly rate in each category of costs when a task can be performed by different levels of professionals. For example, while the revision of compliance policies and procedures can be conducted by either an in-house attorney (average hourly rate $521) or outside counsel (average hourly rate $550), the MSRB chooses the blended hourly rate of $536 for this analysis. Similarly, for training, the MSRB uses the average rate for a Chief Compliance Officer and a compliance attorney; and for ongoing costs, the MSRB uses the hourly rate for a compliance attorney. The number of hours for each task is based on the MSRB's internal estimate.

Reasonable Alternative Approaches and Effects on Competition

One alternative the MSRB considered was to update the qualification requirements of Rule G–3(d)(ii)(B) [41] by changing the existing time for when a person ceases to be associated with a municipal advisor firm from two to five years, instead of from two to three years as currently proposed. Although neither the alternative nor the proposed rule change would permit the granting of a waiver regardless of the time period, individuals would be given greater flexibility when making decisions to temporarily cease their association with municipal advisor firms and can have certainty that they can reassociate with a more limited compliance burden for themselves and the municipal advisor firms.[42] Moreover, a five-year absence from the municipal advisory business could result in a more significant gap in knowledge and experience, and an individual who returns after such an absence may not be fully aware of the latest regulatory and industry changes. The MSRB believes those individuals who cease to engage in municipal advisory activities for more than three years may benefit from retaking the Series 50 examination, which is designed to ensure a baseline level of knowledge exists about rules and regulations, and the regulatory framework in which such individuals operate, as well as to protect municipal entity and obligated person clients who may rely on advice from qualified municipal advisor representatives.

Another alternative the MSRB considered was, instead of requiring CE to include coverage of specific subject areas and topics, an individual would complete catch-up CE for the relevant time period such person ceased association with a municipal advisor firm in order to satisfy the exemption's criteria. The MSRB determined that this alternative would be challenging for solo-practitioners looking to establish a municipal advisor firm because such individuals would not have previous training materials readily available, potentially creating a burden on competition between a solo-practitioner and individuals seeking to join (or reassociate with) existing firms. The MSRB notes that while such solo-practitioners may not have developed CE training materials addressing all of the prescribed subject matters; such firms would be able to utilize ''off-the-shelf content'' or widely available industry educational materials (to the extent such materials meet the requirements set forth in the proposed rule change), which would be a less burdensome approach than creating new CE materials.[43] Thus, the MSRB has deemed the proposed rule change as superior to potential alternative approaches, including for small municipal advisor firms or solo-practitioners.

As previously noted, while an individual and a firm seeking to associate such an individual in the capacity of a municipal advisor principal may receive fewer benefits, still, all municipal advisor firms would benefit from the proposed rule change allowing individuals to requalify in the capacity of municipal advisor representatives.[44] The MSRB acknowledges that there may be a potential burden on competition on solo-practitioners or small municipal advisor firms because the criteria-based exemption does not extend to municipal advisor principals. Specifically, individuals seeking to act as a municipal advisor principal would still have to take and pass the Series 54 examination in order to engage in principal-level activities. Rule G–3(e)(ii)(C) affords temporary relief to an individual (and the municipal advisor firm with which such individual associates) who is qualified as a municipal advisor representative, but is functioning in the capacity of a municipal advisor principal, for a period of 120 days after becoming designated as a municipal advisor principal, to take and pass the Series 54 examination. As a result, all such persons, including those persons seeking to be solo-practitioners and seeking to associate with small (or larger) municipal advisor firms would be able to function in the principal-level capacity for a limited period of time before having to take and pass the Series 54 examination.

Municipal advisor principals are subject to additional regulatory standards given their supervisory, oversight and management duties and the MSRB believes that requiring all municipal advisor principals to requalify by reexamination following a lapse in qualification helps to ensure municipal entity and obligated person protection. Specifically, notwithstanding the fact that small municipal advisor firms may experience a smaller benefit than larger firms, the MSRB believes that reexamination is necessary for all individuals seeking to function in a principal-level capacity. The process of reexamination ensures that the specified level of competency and knowledge of the applicable securities laws and regulations, including MSRB rules, is sufficiently demonstrated. Accordingly, in light of these considerations, the MSRB believes the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act [45] or a regulatory burden on small municipal advisors that is not necessary or appropriate in the public interest and for the protection of investors, municipal entities, and obligated persons, provided that there is robust protection of investors against fraud.[46]

At present, the MSRB cannot evaluate the magnitude of the efficiency gains or losses quantitatively, but believes the overall benefits accumulated over time for market participants would outweigh the minimal upfront and ongoing costs associated with the proposed amendments to Rule G–3 and Rule G–8. The proposed amendments to Rule G–3 would make it easier for individuals seeking to requalify as municipal advisor representatives to reassociate with a municipal advisor firm and for municipal advisor firms to recruit experienced professionals. In addition, the increased number of skilled professionals furthers capital formation because municipal entity and obligated person clients would have ranging areas of expertise to select from when utilizing the services of municipal advisor representatives. Finally, the MSRB believes the proposed amendments to Rule G–3 and Rule G–8 improve the municipal securities

[41] As previously mentioned, Rule G–3(d)(ii)(B) currently provides, ''Any person who ceases to be associated with a municipal advisor for two or more years at any time after having qualified as a municipal advisor representative in accordance with subparagraph (d)(ii)(A) shall take and pass the Municipal Advisor Representative Qualification Examination prior to being qualified as a municipal advisor representative, unless a waiver is granted pursuant to subparagraph (h)(ii) of this rule.''

[42] As noted above, an individual may obtain the criteria-based exemption under the proposed rule change only once.

[43] The MSRB has previously noted that the CE requirements for municipal advisors affords municipal advisors the flexibility to deliver CE in the most convenient and effective manner possible based on the firms' business model. In addition, the MSRB noted industry trade associations may be a good source of CE training materials, in addition to podcasts, webinars and educational materials developed by the MSRB. *See* Exchange Act Release No. 80327 (March 29, 2017), 82 FR 16449, 16454 (April 4, 2017) (Notice of Filing of a Proposed Rule Change to Rule G–3, on Professional Qualification Requirements, and Rule G–8, on Books and Records, To Establish Continuing Education Requirements for Municipal Advisors and Accompanying Recordkeeping Requirements) (File No. SR–MSRB–2017–02).

[44] The MSRB notes, pursuant to Rule G–3(e)(ii), on qualification requirements, the Series 50 examination is a pre-requisite to becoming qualified as a municipal advisor principal.

[45] 15 U.S.C. 78*o*–4(b)(2)(C).

[46] 15 U.S.C. 78*o*–4(b)(2)(L)(iv).

market's operational efficiency and promote regulatory certainty by providing individuals with a specific exemption process to requalify as municipal advisor representatives and to begin engaging in municipal advisory activities on behalf of municipal advisor firms.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

As previously mentioned, the MSRB sought public comment on draft amendments to Rule G–3 in an RFC published on December 1, 2022.[47] The MSRB received three comment letters in response to the RFC.[48] The comments are summarized below by topic and MSRB responses are provided.

General Support for the Proposed Rule Change

All three commenters agreed with the MSRB's assertion that the proposed rule change would benefit, more than burden, municipal advisor firms and would provide increased regulatory flexibility and certainty for municipal advisor representatives and municipal advisor firms. Commenters generally agreed with the requirements for obtaining the criteria-based exemption, including the three-year-minimum-maximum thresholds, as well as the obligation that a municipal advisor firm submit a notice to the MSRB affirming an individual's eligibility for the exemption by having met the criteria enumerated in the proposed rule change.

Continuing Education Criteria

The draft amendments reflected in the RFC would have required that upon associating with a municipal advisor firm, an individual would complete CE consistent with the requirements of current Rule G–3(i)(ii)(B) for the period of time since the individual was last associated with a municipal advisor firm (''CE catch-up requirement''), as part of the criteria-based exemption. In response, NAMA requested clarification on the proposed CE catch-up requirements. NAMA also sought clarification as to how such CE catch-up requirement would be expected to be delivered. NAMA specifically questioned how a solo-practitioner starting their own municipal advisor firm could obtain the exemption since there would be no prior, firm-administered continuing education to deliver to satisfy the CE catch-up requirement.[49] SIFMA also commented that requiring an individual to merely catch up on a firm's previously administered continuing education upon re-entry to the industry may, in practice, result in repetitive, outdated, or confusing information.[50]

In response, the MSRB revised the proposal to make the exemption's CE criteria more practicable and streamlined, so that it is not dependent on previously administered CE. As reflected in the proposed rule change, CE would be required to include coverage of specified subject areas and topics, set forth in the proposal, rather than mandating the completion of previously issued CE for the period of time since the individual seeking to obtain the criteria-based exemption was last associated with a municipal advisor firm.

The MSRB believes that these revisions provide a more practical approach for an individual to comply with the CE requirements in order to qualify for the criteria-based exemption, in that it allows municipal advisor firms to ensure the most useful and up-to-date CE is provided to the individual. At the same time, the revisions would be more workable for solo-practitioners, particularly those establishing a new firm that's never been registered. Since such firms were not previously in existence, they would not have previous CE to provide to take advantage of the draft criteria-based exemption. The revisions, reflected in the proposed rule change, permit such individuals to take advantage of the criteria-based exemption and mitigates the potential for a burden on competition that may otherwise exist between solo-practitioners and those seeking to associate (or reassociate) with an established municipal advisor firm. Finally, the revised approach would permit municipal advisor firms to tailor the required CE training materials to the individual seeking the criteria-based exemption, consistent with the enumerated topic areas in the proposed rule change, to better ensure the most relevant information is covered.

Mechanics of Exemption Requirements

The draft amendments reflected in the RFC would have required that, prior to the individual engaging in municipal advisory activities on behalf of the municipal advisor firm, the firm file a completed SEC Form MA–I on behalf of the individual seeking to obtain the exemption and provide electronic notification to the MSRB that the individual has met the criteria to be exempt from the qualification requirements under the rule.

NAMA commented that further clarification would be beneficial as to timing for completing the CE requirements, when SEC Form MA–I is to be filed, and when the relevant affirmation notification is due to the MSRB.[51] In addition, NAMA suggested that a compliance resource explaining how a solo-practitioner can initially enter or re-enter the municipal securities industry before formally completing the requisite forms to establish a municipal advisor firm (and to associate such individual with the municipal advisor firm) would be beneficial. Relatedly, SIFMA requested that the MSRB consider compliance resources to assist regulated entities (and their associated persons) in understanding the relevant professional qualification and CE requirements, particularly for firms dually registered as a dealer and municipal advisor.[52]

In response, the MSRB revised the proposal (as reflected in the proposed rule change) to address the timing and sequence of satisfying the exemption's criteria, the filing of SEC Form MA–I (and SEC Form MA, as applicable), and the submission of the affirmation notification to the MSRB. Additionally, the MSRB anticipates publishing a compliance resource in close proximity to the compliance date of the rule in response to comments from NAMA and SIFMA, which would highlight the regulatory obligations for municipal advisors and dealers with respect to professional qualification standards, CE requirements, and related registration matters.

Greater Harmonization With FINRA Rules and Related Requirements for Broker-Dealers

SIFMA and NAMA expressed the desire for greater harmonization between the criteria set forth in the draft amendments and the qualification maintenance provisions available to broker-dealers, specifically those under FINRA rules, to reduce regulatory burdens for individuals who serve in

[47] *See supra* note 38.

[48] *See* Letters from Chris Charles, President, Wulff, Hansen & Co. (''Wulff Hansen Letter''), dated December 29, 2022; Susan Gaffney, Executive Director, National Association of Municipal Advisors (''NAMA Letter''), dated January 30, 2023; and Leslie M. Norwood, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association (''SIFMA Letter''), dated January 30, 2023. All comment letters are available at *https://www.msrb.org/sites/default/files/2023-03/All-Comments-to-Notice-2022-13.pdf.*

[49] NAMA Letter at 3–4.

[50] SIFMA Letter at 2.

[51] NAMA Letter at 1.

[52] SIFMA Letter at 2.

multiple registered capacities.[53] The standards related to qualification maintenance for dealers (and their associated persons) were adopted by the MSRB in October 2022.[54] However, there are currently no such prescribed qualification maintenance standards[55] (*e.g.,* required annual CE or requisite hours) for municipal advisor representatives equivalent to the prescribed qualification maintenance standards for municipal securities professionals of dealers.

The proposed rule change seeks to provide municipal advisor representatives with greater flexibility than they have today, which also will provide some parity with the flexibility afforded to dealers. However, the MSRB is mindful of the distinctions between dealers and municipal advisors, including the differences in the applicable qualification maintenance standards as well as the application of a federal fiduciary duty for municipal advisors, but not dealers. After careful consideration, the MSRB continues to believe that the proposed rule change reflects the appropriate balance of flexibility for individuals seeking to requalify without reexamination and for their associated municipal advisor firms with the MSRB's municipal entity protection mandate, as well as the fiduciary duty owed by municipal advisors to their municipal entity clients. The MSRB does not believe that further harmonization with the maintenance qualification standard for dealers (and their associated persons) is appropriate given the distinct nature of municipal advisory activities, including the fiduciary duty owed by municipal advisors to municipal entity clients. In contrast, while dealers are obligated under Rule G–17 to deal fairly with all persons, including municipal entities and obligated persons, they generally engage in arm's-length transactions with such clients and have financial and other interests that may differ from them; therefore, the MSRB believes the three-year mandatory experience requirement and three-year maximum out-of-the-industry requirement recognize the uniqueness of the regulatory framework. Hence, the MSRB determined not to revise the draft proposal to be more consistent with qualification maintenance standards available to dealers.

Application of Exemption to Municipal Advisor Principals

Commenters expressed a belief that the criteria-based exemption from requalification by reexamination should be extended to include municipal advisor principals.[56] After careful consideration, the MSRB continues to believe that such relief should not be extended to municipal advisor principals because the supervisory, oversight and management duties of municipal advisor principals make an exemption from requalification by reexamination inappropriate. Even if such an exemption were contemplated, it would require additional, more stringent criteria than those proposed for municipal advisor representatives to appropriately reflect the heightened responsibilities of a municipal advisor principal. This would result in two different standards and thus additional regulatory complexity in this area.

However, as noted above in relation to the impact of the proposal on solo-practitioners and small municipal advisor firms, solo-practitioners (and individuals associating or re-associating with a firm and designated as a principal) may avail themselves of the provisions under current Rule G–3(e)(ii)(C), which in concert with the proposed rule change, make it possible for a solo-practitioner to start their own firm, requalify as a municipal advisor representative without reexamination and function as a municipal advisor principal for a limited period of time (*i.e.,* 120 days) before having to take and pass the Series 54 examination. Relatedly, for an individual who was once qualified as a municipal advisor principal and who is associating or re-associating with a municipal advisor firm and is expected to take on a principal-level role at the firm, such individual would be able to function in the principal-level capacity for the aforementioned limited period of time before having to take and pass the Series 54 examination.

Other Comments Considered

Wulff Hansen objected to the criterion that would have prohibited an individual seeking the exemption from engaging in municipal advisory activities during a lapse in qualification. Wulff Hansen noted that such a prohibition does not recognize that the SEC permits certain individuals to engage in municipal advisory activities without registration because they qualify for an exclusion or exemption from registration requirements, for example, the underwriter exclusion, as prescribed under Section 15B(e)(4)(C) of the Act (15 U.S.C. 78*o*–4(e)(4)(C)).[57] In response to this comment, the revisions reflected in the proposed rule change clarify that an individual must not have engaged in activities requiring qualification as a municipal advisor representative during the individual's lapse in qualification.

Wulff Hansen also suggested that the MSRB retain the ability to grant waivers for individuals in highly exceptional circumstances that do not qualify for the criteria-based exemption set forth in the draft amendments.[58] The MSRB believes that retention of such a waiver process is unnecessary in light of how few waiver requests the Board has received.[59] Additionally, as discussed above, the MSRB believes that municipal advisor principals should be required to take and pass the requisite qualification examination in light of the heightened responsibilities performed by such persons. Finally, the MSRB believes that retention of such a waiver provision would result in less objective and predictable requalification standards than those provided for in the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period of up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–MSRB–2023–05 on the subject line.

[53] SIFMA Letter at 1–2; NAMA Letter at 5.

[54] *See* Exchange Act Release No. 95684 (September 7, 2022), 87 FR 56137 (September 13, 2022) (File No. SR–MSRB–2022–07).

[55] *See* Rules G–3(a)(ii)(C), G–3(b)(ii)(C), G–3(b)(iv)(B)(3), G–3(c)(ii)(C) and G–3(i)(i)(C) for qualification maintenance standards applicable to dealers.

[56] NAMA Letter at 4–5; SIFMA Letter at 2; and Wulff Hansen Letter at 3.

[57] Wulff Hansen Letter at 1.

[58] *Id.* at 2.

[59] *Supra* note 37.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549.

All submissions should refer to File Number SR–MSRB–2023–05. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the MSRB. 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–MSRB–2023–05 and should be submitted on or before August 21, 2023.

For the Commission, pursuant to delegated authority.[60]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16109 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[60] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97986; File No. SR–CboeBYX–2023–011]

Self-Regulatory Organizations; Cboe BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rules To Provide Users With a Risk Setting They May Elect To Apply to Their Orders That Will Allow Them To Reject Market Orders During Continuous Trading and/or Auctions

July 25, 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 July 14, 2023, Cboe BYX Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BYX Exchange, Inc. (''BYX'' or the ''Exchange'') is filing with the Securities and Exchange Commission (the ''Commission'') a proposal to amend Interpretation and Policy .01 to Rule 11.13 in connection with a risk setting that Users[3] may elect to apply to their orders that will allow them to reject market orders during continuous trading and/or auctions.[4] The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Exchange's website (*http://markets.cboe.com/us/equities/regulation/rule_filings/byx/*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this proposal is to amend Interpretation and Policy .01 to Rule 11.13 to allow the Exchange to offer its Users the ability to apply a risk setting to their orders that will allow them to reject market orders during continuous trading or auctions (''Market Order Check''). Pursuant to Interpretation and Policy .01 to Rule 11.13, the Exchange currently offers certain optional risk settings applicable to a User's activities on the Exchange. Specifically, pursuant to Interpretation and Policy .01(c) to 11.13, the Exchange currently offers Users with the controls to restrict order types or modifiers that can be utilized (including pre-market, post-market, short sales, ISOs, and Directed ISOs). When utilized, this optional risk tool acts as a risk filter by evaluating a User's orders to determine whether the orders comply with certain criteria established by the User.

Based on feedback from its Members, the Exchange now seeks to expand this risk setting to allow a User to restrict additional order types from being entered—market orders during continuous trading and/or market orders during auctions (''Market Order Check'').[5] The Market Order Check will reside at a User's port level, a User-specific logical session used to access the Exchange. A User may utilize the Market Order Check to control the acceptance of, or rejection of, its inbound market orders. Similarly, a Sponsoring Member[6] may utilize the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] A User is any Member or Sponsored Participant who is authorized to obtain access to the System pursuant to Rule 11.13. *See* Rule 1.5(cc).

[4] The Exchange plans to implement the proposed rule change on a date that will be circulated in a notice from the Cboe Trade Desk to all Members.

[5] The Exchange notes that the proposed Market Order Check will treat Stop Orders as regular market orders. A ''Stop Order'' Stop Order is an order that becomes a BYX market order when the stop price is elected. A Stop Order to buy is elected when the consolidated last sale in the security occurs at, or above, the specified stop price. A Stop Order to sell is elected when the consolidated last sale in the security occurs at, or below, the specified stop price. *See* Rule 11.9(c)(16), definition of ''Stop Order''.

[6] The term ''Sponsoring Member'' shall mean a broker-dealer that has been issued a membership by the Exchange who has been designated by a Sponsored Participant to execute, clear and settle transactions resulting from the System. The Sponsoring Member shall be either (i) a clearing

check to control the acceptance of, or rejection of, its Sponsored Participants [7] inbound market orders. Specifically, when utilized the Market Order Check will allow a User to (1) permit market orders; (2) reject market orders during continuous trading and allow market orders during auctions, or (3) reject market orders during continuous trading and also during auctions. In the case of Sponsored Participants, the Sponsoring Member will be responsible for their Sponsored Participant's Market Order Check settings. The Market Order Check will apply only to equities orders and will not apply to market on open or market on close orders. The proposed Market Order Check is similar in nature to the Order Type/Attribution check offered by Nasdaq Stock Exchange, LLC (''Nasdaq''), which prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders.[8] While the proposed Market Order Check differs slightly from that offered by Nasdaq in that it includes functionality that prohibits the entry of both auction and non-auction market orders, the intended purpose of the control—a risk management tool designed to prevent the entry of orders that may cause undue market impact—remains the same.

Importantly, as is the case with the existing risk settings, the User, and not the Exchange, will have the full responsibility for ensuring that their orders comply with applicable securities rules, laws, and regulations. Furthermore, the Exchange does not believe that the use of the Market Order Check can replace User-managed risk management solutions, and use of the Market Order Check does not automatically constitute compliance with Exchange rules.

The Exchange proposes to make the risk setting available to its Users upon request and will not require Users to utilize the Market Order Check. The Exchange will not provide preferential treatment to Users utilizing the Market Order Check. However, the Exchange believes the Market Order Check will offer Exchange Users another option in efficient risk management of its access to the Exchange. For instance, the Market Order Check may assist some Users in mitigating the risk of receiving executions at unfavorable prices due to market fluctuations and/or available liquidity in the subject security. Similarly, the Market Order Risk Check may serve as a supplemental tool for Sponsoring Members to ensure that market orders entered by their Sponsored Participants do not unexpectedly cause undue impact to the market for a security, which may occur when the market fluctuates, and an order executes at prices significantly different from the price of the security at the time of order entry.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the requirements of Section 6(b) of the Act,[9] in general, and Section 6(b)(5) of the Act,[10] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to, and perfect the mechanism of, a free and open market and a national market system and, in general, to protect investors and the public interest. Period footnote throughout [sic]

Specifically, the proposed Market Order Check is designed to protect investors and the public interest because it will provide Users with a tool to help prevent the entry of market orders that may cause unintentional market impact, and reduce the potential for disruptive, market-wide events. The proposed Market Order Check may also assist Users in managing their financial exposure by preventing executions at unfavorable prices, thereby fostering the integrity of trading on the securities markets and helping to assure the stability of the financial system. Finally, the Exchange believes that the proposed rule change does not unfairly discriminate among the Exchange's Users because like each of the other Exchange's risk settings, use of the Market Order Check is optional and available to all Users, and its use is not a perquisite for participation on the Exchange.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change imposes any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Rather, the proposed Market Order Check will foster competition because it would allow the Exchange to offer a risk check that is similar to functionality being offered by Nasdaq,[11] which offers an order type/attribution check that prevents the entry of certain order types or modifiers that can be utilized, including but not limited to, non-auction market orders. Additionally, by providing Users with additional means to monitor and control their risk, the proposed Market Order Check may enhance proper functioning of the markets and contribute to additional competition among trading venues and broker-dealer dealers. Finally, the proposed Market Order Check will enable Users to strengthen their risk management capabilities, which, in turn, may enhance the integrity of trading on the securities markets and help to assure the stability of the financial system.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposal. No written comments were solicited or received on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not (A) significantly affect the protection of investors or the public interest; (B) impose any significant burden on competition; and (C) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act [12] and Rule 19b–4(f)(6) [13] thereunder.

firm with membership in a clearing agency registered with the Commission that maintains facilities through which transactions may be cleared or (ii) a correspondent firm with a clearing arrangement with any such clearing firm. *See* Rule 1.5(y), definition of, ''Sponsoring Member''.

[7] The term ''Sponsored Participant'' shall mean a person which has entered into a sponsorship arrangement with a Sponsoring Member pursuant to Rule 11.3. *See* Rule 1.5(x), definition of, ''Sponsored Participant''.

[8] *See* Nasdaq Equity 6, Section 5. Risk Settings (b), ''Order Type/Attribution Check—This control relates to the order types or modifiers that can be utilized (including pre-market, post-market, short sales, non-auction market orders and Intermarket Sweep Orders)'', available at: *https://listingcenter.nasdaq.com/rulebook/Nasdaq/rules/Nasdaq%20Equity%206/market%20impact%20check/EQUALS/#position; see also* Securities Exchange Act Release No. 34–95495 (August 12, 2022), 87 FR 50902 (August 18, 2022) (SR–NASDAQ–2022–047) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Nasdaq Equity 6, Section 5).

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(5).

[11] *Supra* note 10.

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change,

Continued

A proposed rule change filed under Rule 19b–4(f)(6) [14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may designate a shorter time if such action is consistent with the protection of investor and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposed rule change may become operative upon filing. The Exchange states that waiver of the 30-day operative delay will allow the Exchange to immediately offer its Users an additional means to mitigate unintended market impact, thus fostering the protection of investors and the public interest. Because the proposed rule change does not raise any novel regulatory issues, the Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.[16]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBYX–2023–011 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–CboeBYX–2023–011. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549, on official business days between the hours of 10 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBYX–2023–011 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16111 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

[17] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97980; File No. SR–IEX–2023–07]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend IEX Rule 2.160 To Provide Eligible Individuals Another Opportunity To Elect To Participate in the Maintaining Qualifications Program

July 25, 2023.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (the ''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 13, 2023, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Act,[4] and Rule 19b–4 thereunder,[5] IEX is filing with the Commission a proposed rule change to amend IEX Rule 2.160 to provide eligible individuals another opportunity to elect to participate in the Maintaining Qualifications Program. The Exchange has designated this proposal as non-controversial pursuant to Section 19(b)(3)(A)(iii) of the Act [6] and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) thereunder.[7]

The text of the proposed rule change is available at the Exchange's website at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CFR 240.19b–4.

[6] 15 U.S.C. 78s(b)(3)(A).

[7] 17 CFR 240.19b–4(f)(6)(iii).

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 self-regulatory organization 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

IEX is proposing to amend Supplementary Material .01 to IEX Rule 2.160(p)(c) to provide eligible individuals another opportunity to elect to participate in in the Maintaining Qualifications Program (''MQP''). This proposed rule change is based on a substantively identical filing made by the Financial Industry Regulatory Authority, Inc. (''FINRA''), which established a second enrollment period for the MQP that ends on December 31, 2023 (''Second Enrollment Period'').[8]

On November 28, 2022, IEX amended IEX Rule 2.160 to, among other things, provide eligible individuals who terminate any of their representative or principal registration categories the option of maintaining their qualification for any terminated registration categories by completing annual continuing education through the new MQP.[9] By that time, however, the First Enrollment Period, defined below, had expired leaving many eligible individuals unable to participate in the MQP. This proposed rule change will provide those eligible individuals a second opportunity to elect to participate in the MQP to maintain their qualifications.

Prior to the MQP, individuals whose registrations as representatives or principals had been terminated for two or more years could reregister as representatives or principals only if they requalified by retaking and passing the applicable representative or principal-level examination or if they obtained a waiver of such examination(s) (the ''two-year qualification period''). The MQP provides these individuals an alternative means of staying current on their regulatory and securities knowledge following the termination of a registration.[10] Specifically, the MQP provides eligible individuals a maximum of five years following the termination of a representative or principal registration category to reregister without having to requalify by examination or having to obtain an examination waiver, subject to satisfying the conditions and limitations of the MQP, including the annual completion of all prescribed continuing education.

Supplementary Material .01 to IEX Rule 2.160(p)(c) (Eligibility of Other Persons to Participate in the Continuing Education Program Specified in Subparagraph (c) of Rule 2.160(p)), describes a look-back provision that extended the option of participating in the MQP to individuals who: (1) were registered in a representative or principal registration category with FINRA within two years immediately preceding March 15, 2022; or (2) were participating in the Financial Services Affiliate Waiver Program (''FSAWP'')[11] pursuant to Supplementary Material .01 to Rule 2.160(g) immediately preceding March 15, 2022 (collectively, ''Look-Back Individuals'').

In the FINRA MQP Second Enrollment Period Filing, FINRA noted that in Regulatory Notice 21–41 (November 17, 2021), it announced that Look-Back Individuals who wanted to take part in the MQP were required to make their election between January 31, 2022, and March 15, 2022 (the ''First Enrollment Period''). In addition to the announcement in Regulatory Notice 21–41, FINRA notified the Look-Back Individuals about the MQP and the First Enrollment Period via two separate mailings of postcards to their home addresses and communications through their FINRA Financial Professional Gateway (''FinPro'') accounts.[12] In that same filing, FINRA noted that shortly after the First Enrollment Period ended, a number of Look-Back Individuals contacted FINRA and indicated that they had only recently become aware of the MQP.[13] In addition, FINRA noted that the original six-week enrollment period may not have provided Look-Back Individuals with adequate time to evaluate whether they should participate in the MQP.[14] Thus, FINRA both established a Second Enrollment Period for the MQP, which lasts until December 31, 2023, and set forth a robust communication campaign involving more active outreach to enhance public awareness of Second Enrollment Period for the MQP.[15]

IEX, like FINRA, believes that greater public awareness of the MQP and FINRA's additional outreach efforts, coupled with the longer duration of the Second Enrollment Period (the first enrollment period last six weeks), should help notify as many Look-Back-Individuals as possible of their options with respect to the MQP, and should provide them ample time to decide whether to participate in the MQP.[16]

Thus, IEX proposes to amend Supplementary Material .01 to IEX Rule 2.160(p)(c) to conform with FINRA's recent amendments to FINRA Rule 1240.01. Specifically, IEX proposes to add language stating that persons eligible for the MQP look-back period either: (i) had to elect to participate with FINRA in the MQP by March 15, 2022, or (ii) shall make their election to participate with IEX in the MQP during a new enrollment period that begins on [date of the filing] and ends on December 31, 2023. IEX also proposes to add language stating that Look-Back Individuals who participate in the MQP shall have a participation period of five years following the termination of their registration categories, and that they must complete any prescribed 2022 and 2023 continuing education content by March 31, 2024.[17] Lastly, IEX proposes to delete the last sentence of Supplementary Material .01 to IEX Rule 2.160(p)(c) that describes how FINRA adjusted participation periods for individuals who enrolled in the MQP during the first enrollment period.

Look-Back Individuals who elect to enroll during the Second Enrollment Period would need to notify FINRA of their election to participate in the MQP through their FinPro accounts.[18] IEX also notes that Look-Back Individuals who elect to participate in the MQP during the Second Enrollment Period

[8] *See* Securities Exchange Act Release No. 97184 (March 22, 2023) 88 FR 18359 (March 28, 2023) (SR–FINRA–2023–005) (''FINRA MQP Second Enrollment Period Filing'').

[9] *See* Securities Exchange Act Release No. 96473 (December 9, 2022) 87 FR 77152 (December 16, 2022) (SR–IEX–2022–11).

[10] The MQP does not eliminate the two-year qualification period. Thus, eligible individuals who elect not to participate in the MQP can continue to avail themselves of the two-year qualification period (*i.e.,* they can reregister within two years of terminating a registration category without having to requalify by examination or having to obtain an examination waiver).

[11] The FSAWP is a waiver program for eligible individuals who have left a member firm to work for a foreign or domestic financial services affiliate of a member firm. FINRA stopped accepting new participants for the FSAWP beginning on March 15, 2022; however, individuals who were already participating in the FSAWP prior to that date had the option of continuing in the FSAWP.

[12] Look-Back Individuals were able to notify FINRA of their election to participate in the MQP through their FinPro accounts.

[13] *See supra* note 8.

[14] *See Id.*

[15] *See Id.*

[16] *See Id.*

[17] Look-Back Individuals who elect to enroll in the MQP during the Second Enrollment Period would also need to pay the annual program fee of $100 for both 2022 and 2023 at the time of their enrollment.

[18] *See* Second Enrollment Period, *https://www.finra.org/registration-exams-ce/continuing-education/CE-transformation/mqp#Second-Enrollment.*

would continue to be subject to all of the other MQP eligibility and participation conditions. For example, as clarified in the proposed rule change, Look-Back Individuals electing to participate during the Second Enrollment Period would have only a maximum of five years following the termination of a registration category in which to reregister without having to requalify by examination or having to obtain an examination waiver.[19]

IEX has filed the proposed rule change for immediate effectiveness and has requested that the Commission waive the 30-day operative delay. The operative date will be the date of the filing of the proposed rule change if the Commission grants the waiver.

2. Statutory Basis

The Exchange believes that its proposal is consistent with the requirements of Sections 6(b)[20] and 6(b)(5) of the Act,[21] in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. IEX believes that providing Look-Back Individuals a second opportunity to elect to participate in the MQP is warranted because participation in the MQP would reduce unnecessary impediments to requalification for these individuals without diminishing investor protection. In addition, the proposed rule change is consistent with other goals, such as the promotion of diversity and inclusion in the securities industry by attracting and retaining a broader and diverse group of professionals. The MQP also allows the industry to retain expertise from skilled individuals, protecting investors with the advantage of greater experience among individuals working in the industry. IEX believes that providing Look-Back Individuals a second opportunity to elect to participate in the MQP will further these goals and objectives.

The Exchange believes the proposed rule change is consistent with the provisions of Section 6(b)(5) of the Act,[22] which requires, among other things, that Exchange Rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 6(c)(3) of the Act,[23] which authorizes the Exchange to prescribe standards of training, experience and competence for persons associated with Exchange.

Finally, as described in the Purpose section, the proposed rule change seeks to align the Exchange Rules with changes to FINRA rules which have been allowed to take effect by the Commission.[24] Thus, this rule change raises no novel issues that have not already been considered by and accepted by the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the proposed rule change, which harmonizes its rules with rule changes adopted by FINRA, will reduce the regulatory burden placed on market participants engaged in trading activities across different markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

IEX has filed the proposed rule change pursuant to Section 19(b)(3)(A) of the Act[25] and Rule 19b–4(f)(6) thereunder.[26] Because the proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

A proposed rule change filed under Rule 19b–4(f)(6)[27] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b4(f)(6)(iii),[28] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. IEX has indicated that the immediate operation of the proposed rule change is appropriate because it would allow the Exchange to implement the proposed changes to its continuing education rules without delay, thereby eliminating the possibility of a significant regulatory gap between the FINRA rules and the Exchange rules, providing more uniform standards across the securities industry, and helping to avoid confusion for Exchange members that are also FINRA members. IEX also noted that FINRA plans to conduct additional public outreach efforts to promote awareness of the MQP and the availability of the Second Enrollment Period among Look-Back Individuals. Therefore, IEX indicated that the immediate operation of the proposed rule change is also appropriate because it would help to further notify Look-Back Individuals of their options and provide additional time for them to consider whether they wish to participate in the MQP program before the December 31, 2023 deadline. For these reasons, the Commission believes that waiver of the 30-day operative delay for this proposal is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[29]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[30] of the Act to

[19] For example, if a Look-Back Individual terminated a registration category on May 1, 2020, and elects to participate in the MQP on December 1, 2023, the individual's maximum participation period would be five years starting on May 1, 2020, and ending no later than May 1, 2025. If the individual does not reregister with a member firm by May 1, 2025, the individual would need to requalify by examination or obtain an examination waiver in order to reregister after that date.

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78f(b)(5).

[23] 15 U.S.C. 78f(c)(3).

[24] *See supra* note 8.

[25] 15 U.S.C. 78s(b)(3)(A)(iii).

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule change's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78s(b)(2)(B).

determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2023–07 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–IEX–2023–07. 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 such 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–IEX–2023–07 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–16107 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97974; File No. SR–ICEEU–2023–018]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Proposed Rule Change, as Modified by Amendment No. 1 and Partial Amendment No. 2, Relating to Amendments to the Outsourcing Policy

July 25, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 10, 2023, ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule changes described in Items I, II and III below, which Items have been primarily prepared by ICE Clear Europe. On July 11, 2023, ICE Clear Europe filed Amendment No. 1 to the proposed rule change to make certain changes to the Form 19b–4 and Exhibit 1A for file no. SR–ICEEU–2023–018.[3] On July 24, 2023, ICE Clear Europe filed Partial Amendment No. 2 to the proposed rule change to make a certain change to Exhibit 5 of file no. SR–ICEEU–2023–018.[4] The Commission is publishing this notice to solicit comments on the proposed rule change, as modified by Amendment No. 1 and Partial Amendment No. 2 (hereafter, ''the proposed rule change''), from interested persons.

I. Clearing Agency's Statement of the Terms of Substance of the Proposed Rule Change

ICE Clear Europe Limited (''ICE Clear Europe'' or the ''Clearing House'') is proposing to amend its Outsourcing Policy (to be renamed the Outsourcing and Third Party Risk Management Policy) (the ''Outsourcing Policy'' or ''Policy'').[5] The amendments would broaden the coverage of the Policy to address third party service provider arrangements that may not technically constitute outsourcing, to enhance third party risk management, to add the execution of risk assessments and to update the Document Governance and Exception Handling language, among other changes discussed herein.

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe 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. ICE Clear Europe has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

(A) Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe is proposing to amend its Outsourcing Policy (to be renamed the Outsourcing and Third Party Risk Management Policy) to extend coverage of the policy to include risk management of third party arrangements that may not constitute outsourcing. The purpose of the Policy would reflect this change by clarifying that the Policy would generally extend to arrangements in which services are provided by third parties to the Clearing House, whether or not such services are considered outsourcing, including to assessing the risks of such services.

The Outsourcing Policy would clarify its definition of outsourcing in the introduction section to be the use of third party service providers (which could be an external party or an affiliate), either directly or through sub-outsourcing, to provide a service that would otherwise be performed by ICE Clear Europe itself and is therefore subject to the Board's oversight. The amendment would further clarify that the Clearing House would remain responsible for discharging its obligations with respect to the outsourced activities, the outsourcing arrangement would not result in the

---

[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 amends and restates in its entirety the Form 19b–4 and Exhibit 1A to correct the narrative description of the proposed rule change. Amendment No. 1 did not change the purpose or basis of the proposed rule change.

[4] Partial Amendment No. 2 amends and restated in its entirety Exhibit 5 to correct an inadvertent omission of a single word. Partial Amendment No. 2 did not change the purpose or basis of the proposed rule change.

[5] Capitalized terms used but not defined herein have the meanings specified in the ICE Clear Europe Clearing Rules and the Outsourcing Policy.

delegation of the Clearing House's responsibility, and the outsourced activities would conform to the same standards that would be required if the activities were completed internally. The amendments would also clarify the distinction between an outsourcing and a purchasing arrangement, which would not involve an arrangement otherwise performed by the Clearing House and therefore would not typically be subject to Board oversight.

The amendments would also clarify the distinction between external third party providers of services and affiliated providers. The Policy would add a definition for third party, which would cover any organization (whether or not affiliated) that has entered into a relationship or contract with the Clearing House to provide products, services, processes, activities or business functions. Use of external third parties (*i.e.,* those not affiliated with the Clearing House) would be managed consistently at the group level through the existing Vendor Management Policy (''VMP''). It would further clarify that outsourcing through the Clearing House's affiliates presents a lower residual risk profile because, among listed reasons in the existing Policy, the affiliates would have a similar higher standard of operational resilience generally (as opposed to referring only to business continuity) and the Clearing House would also have greater influence (as well as control) over the operation of the affiliate's services. These amendments are intended to more clearly describe current practice under the existing Policy.

The amendments would revise statements in the existing Policy relating to objectives, assessments of service providers in various situations (including regulated parties and parties in different jurisdictions), management of outsourcing, conflicts of interest and audit to also extend to other third party service arrangements. The amendments would reference the Clearing House's outsourcing operating manual (renamed to reflect the broader goal of third party risk management as well of outsourcing). As so revised, the Policy would state that contracting with third parties is covered consistently at a group level under the VMP. The amendments would clarify, consistent with current practice, that ICE Clear Europe would use the VMP process as an input for the risk-based assessment of each service provider. The amendments would also provide that the Clearing House would make the third parties aware of relevant internal policies to gain a better understanding of the obligations and services expected. For contracting with affiliates, the amendments would clarify that the relevant assessment would be made by ICE Clear Europe, in accordance with its ordinary governance practices (and not necessarily by the senior management). The revised Policy would state that ICE Clear Europe would follow its Conflicts of Interest Policy when managing any potential conflicts of interests as a result of its service arrangements. (This reflects current practice but would add an appropriate reference in the Policy to the Conflicts of Interest Policy.) With respect to cloud outsourcing, the amendments would add that ICE Clear Europe would consider any risks related to the Clearing Members connecting to the Clearing House through cloud service providers.

The Policy would also include a new Risk Assessments section that would set out the proportional risk assessment that would be performed on a service provider in order to identify, measure and mitigate risks. The section would include certain considerations (although not limited to those listed) that include whether the service is a critical or important function or a dependence to the delivery of one of ICE Clear Europe's services, whether the activity is outsourcing, whether the service relies on cloud-based technology that may pose new or additional risks, whether the service provider is an external third party or an affiliate, the legal jurisdiction of the service provider, conflicts of interest, operational resilience considerations, data security, exit plans, contractual terms, and availability of alternative or back-up providers, among others. For outsourced or critical non-outsourced services, this assessment would be performed at least annually and on an ad-hoc basis following a material incident or service disruption event or material service agreement breach. This would include comparing the performance of the service provider against the agreed service levels. The responsibilities of risk assessments and related testing would be overseen by the Clearing House's Chief Operating Officer or delegate, with ownership of each service and the related resiliency arrangements resting with the relevant Head of Department.

The amendments would clarify and expand certain provisions relating to identification of critical or important functions, including to extend the existing provisions to apply to acquired services generally and not only outsourcing. In identifying critical or important functions the amendments would add that the Clearing House would consider continuity of ICE Clear Europe's important business services or operation as a CCP that could in turn threaten the Clearing House's financial stability or impact its resolvability. A third party would be treated as critical if it is contracted to perform such a critical function. Criticality would be reassessed on at least an annual basis.

The revised Policy would also acknowledge that any outsourcing of critical or important functions could have an effect on the operational resilience measures of the Clearing House more generally (and not merely the narrower category of business continuity). The revised Policy further clarifies that exit plans for critical and important functions would be periodically tested. As part of its operational resilience framework, the Clearing House would examine purchased services as well as outsourced or sub-outsourced services that are a dependence for the Clearing House's important business services. In addition, the operational resilience framework would include extreme but plausible test scenarios resulting from the disruption of critical third party services.

The Policy would also make various amendments to the discussion of additional important considerations for the Clearing House to ensure that considerations would be given to important business services and critical functions that are affected by third party service arrangements, including with respect to business continuity arrangements, incident management responsiveness and reporting, independent assurances, redundancies, notice periods and exit strategies. The amendments would add a new section on Contractual Agreements. The section would add that for outsourcing arrangements in particular, the Clearing House's legal team would review any written service agreements to confirm the inclusion of all relevant contractual safeguards so that ICE Clear Europe could monitor relevant risks, regulatory requirements and expectations. The aim would be for the agreements to outline the rights, obligations, and responsibilities of all the parties, and include provisions associated with data security, access, audit and information rights, sub-outsourcing, service resilience, service levels, incident management, termination and exit plans. Arrangements for purchased services should be similarly reviewed, but the Policy would acknowledge that some purchased services may be subject to non-negotiable terms set by the third party. This situation would be considered during the pre-execution risk assessment phase. The Outsourcing

Policy would also set out that ICE Clear Europe would periodically exercise its audit rights under agreements relating to outsourcing arrangements, perform audits as appropriate which could include on-site visits.

Provisions relating to Board oversight would be revised to provide that the Board must approve new or materially amended outsourcing arrangements. Certain clarifications would be made to the requirements for the annual outsourcing assessment report to be prepared by the Chief Operating Officer, including the addition of a summary of critical non-outsourcing services received. A new provision would be added setting out that ICE Clear Europe will engage with regulatory authorities before executing or materially amending a critical service arrangement with regard to the relevant regulatory requirements or expectations.

Finally, the amendments would make changes to the Policy's document governance, breach management and exception handling, to make it generally consistent with other ICE Clear Europe policies. The document owner identified by the Clearing House would be responsible for ensuring that the Policy remains up-to-date and reviewed in accordance with the Clearing House's governance processes. Document review would be conducted by the document owner and related staff, with sign off by the head of department and the Chief Risk Officer (or their respective delegates). Document reviews would encompass at the minimum regulatory compliance, documentation and purpose, implementation, use and open items from previous validations or reviews. Results of the review would have to be reported to the Executive Risk Committee or in certain cases to the Model Oversight Committee. The document owner would also aim to remediate the findings, complete internal governance and receive regulatory approvals before the following annual review is due. The document owner would also be responsible for reporting any material breaches or deviations to the Head of Department, Chief Risk Officer and Head of Regulation and Compliance in order to determine if further escalation is required. The amendments would state explicitly that changes to the Policy would have to be approved in accordance with the Clearing House's governance process and would take effect following completion of required internal and regulatory approvals. Exceptions to the Policy would also be approved in accordance with the governance processes for approvals of changes to the Policy.

(b) Statutory Basis

ICE Clear Europe believes that the amendments to the Outsourcing Policy are consistent with the requirements of Section 17A of the Securities Exchange Act of 1934 (the ''Act'')[6] and the regulations thereunder applicable to it. In particular, Section 17A(b)(3)(F) of the Act[7] requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and, to the extent applicable, derivative agreements, contracts, and transactions, the safeguarding of securities and funds in the custody or control of the clearing agency or for which it is responsible, and the protection of investors and the public interest.

The changes to the Outsourcing Policy are designed to extend coverage of the existing policy to include third party risk management more generally, including purchased services as well as outsourced services. The amendments also add new requirements around risk assessments, identification of critical functions, operational resilience, and review of contractual arrangements with service providers. The amendments further update the Board oversight, document governance, regulatory engagement, and exception handling. The amendments would not make changes to the Rules or the rights or obligations of Clearing Members. In ICE Clear Europe's view, the amendments to the Policy will thus facilitate management of the risks related to outsourcing and other third party service arrangements, and thereby promote the efficient operation and stability of the Clearing House and the prompt and accurate clearance and settlement of cleared contracts. The enhanced risk management for third party service providers is therefore also generally consistent with the protection of investors and the public interest in the safe operation of the Clearing House. (ICE Clear Europe would not expect the changes to the Policy to affect materially the safeguarding of securities and funds in ICE Clear Europe's custody or control or for which it is responsible.) Accordingly, the amendments to the Policy satisfy the requirements of Section 17A(b)(3)(F).[8]

The amendments to the Outsourcing Policy are also consistent with relevant provisions of Rule 17Ad–22.[9] Rule 17Ad–22(e)(3)(i) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable [sic] designed to, as applicable [. . .] identify, measure, monitor, and manage the range of risks that arise in or are borne by the covered clearing agency''.[10] The amendments to the Policy are intended to better document and to enhance the Clearing House's practices that relate to management of the Clearing House's use of outsourcing and other third party service providers, as set forth above. The changes to the Outsourcing Policy aim to extend certain Clearing House risk management practices to third party services that may not be covered by existing outsourcing practices. In ICE Clear Europe's view, as set out above, the amended Policy would facilitate overall risk management with respect to third party services, consistent with the requirements of Rule 17Ad–22(e)(3)(i).[11]

Rule 17Ad–22(e)(2) provides that ''[e]ach covered clearing agency shall establish, implement, maintain and enforce written policies and procedures reasonable [sic] designed to, as applicable [. . .] provide for governance arrangements that are clear and transparent''[12] and ''[s]pecify clear and direct lines of responsibility''.[13] As discussed, the amendments to the Policy would update the provisions relating to Board oversight, including by stating that the Board must approve new or materially amended outsourcing arrangements. The amendments would also state more clearly requirements around document governance, regulatory engagement, and exception handling, generally in a manner consistent with other ICE Clear Europe policies. The Policy would describe the responsibilities of the document owner and appropriate escalation and notification requirements for responding to exceptions and deviations from the Policy. In ICE Clear Europe's view, the amendments are therefore consistent with the requirements of Rule 17Ad–22(e)(2).[14]

(B) Clearing Agency's Statement on Burden on Competition

ICE Clear Europe does not believe the amendments to the Outsourcing Policy would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. The Policy changes are being adopted to better document and enhance the Clearing House's

[6] 15 U.S.C. 78q–1.

[7] 15 U.S.C. 78q–1(b)(3)(F).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 17 CFR 240.17 Ad–22.

[10] 17 CFR 240.17 Ad–22(e)(3)(i).

[11] 17 CFR 240.17 Ad–22(e)(3)(i).

[12] 17 CFR 240.17 Ad–22(e)(2)(i).

[13] 17 CFR 240.17 Ad–22(e)(2)(v).

[14] 17 CFR 240.17 Ad–22(e)(2).

practices related to risk management of third party service providers, including purchased services as well as outsourcing. The Policy does not change the rights or obligations of Clearing Members or the Clearing House under the Rules or Procedures. Accordingly, ICE Clear Europe does not believe that adoption of the Policy would adversely affect competition among Clearing Members, materially affect the costs of clearing, adversely affect the ability of market participants to access clearing or the market for clearing services generally, or otherwise adversely affect competition in clearing services. Therefore, ICE Clear Europe does not believe the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed amendments have not been solicited or received by ICE Clear Europe. ICE Clear Europe will notify the Commission of any written comments received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change, security-based swap submission or advance notice 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–ICEEU–2023–018 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–ICEEU–2023–018. 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 10:00 a.m. and 3:00 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's website at *https://www.theice.com/clear-europe/regulation.*

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–ICEEU–2023–018 and should be submitted on or before August 21, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

J. Matthew DeLesDernier,

Deputy Secretary.

[FR Doc. 2023–16118 Filed 7–28–23; 8:45 am]

BILLING CODE 8011–01–P

[15] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration # 18030; COLORADO Disaster Number CO–00142 Declaration of Economic Injury]

Administrative Declaration of an Economic Injury Disaster for the State of Colorado

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Economic Injury Disaster Loan (EIDL) declaration for the State of Colorado dated 07/25/2023.

Incident: Colorado Highway 133 Sinkhole and Road Closure.

Incident Period: 05/02/2023 through 06/19/2023.

DATES: Issued on 07/25/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 04/25/2024.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's EIDL declaration, applications for economic injury disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Delta, Garfield, Gunnison.

Contiguous Counties:

Colorado: Chaffee, Eagle, Hinsdale, Mesa, Montrose, Ouray, Pitkin, Rio Blanco, Routt, Saguache.

Utah: Grand, Uintah.

The Interest Rates are:

	Percent
Businesses and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for economic injury is 180300.

The States which received an EIDL Declaration #18030 are Colorado, Utah.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–16086 Filed 7–28–23; 8:45 am]

BILLING CODE 8026–09–P

SURFACE TRANSPORTATION BOARD

[Docket No. EP 519 (Sub-No. 4)]

Notice of National Grain Car Council Meeting

AGENCY: Surface Transportation Board.

ACTION: Notice of National Grain Car Council meeting.

SUMMARY: Notice is hereby given of a meeting of the National Grain Car Council (NGCC), pursuant to the Federal Advisory Committee Act.

DATES: The meeting will be held on Thursday, August 15, 2023, beginning at 1:00 p.m. (CDT), and is expected to conclude at 5:00 p.m. (CDT).

ADDRESSES: The meeting will be held at the InterContinental Kansas City at the Plaza, 401 Ward Parkway, Kansas City, MO 64112. Phone (816) 756–1500.

FOR FURTHER INFORMATION CONTACT: Alan Cassiday at (202) 245–0308, (717) 215–0635, or *alan.cassiday@stb.gov.*

SUPPLEMENTARY INFORMATION: The NGCC was established by the Interstate Commerce Commission (ICC) as a working group to facilitate private-sector solutions and provide recommendations to the ICC (and now the Surface Transportation Board (Board)) on matters affecting rail grain car availability and transportation. *Nat'l Grain Car Supply—Conference of Interested Parties,* EP 519 (ICC served Jan. 7, 1994).

The general purpose of this meeting is to discuss rail carrier preparedness to transport the 2023 grain harvest. Agenda items include the following: remarks by NGCC Chair Shane Berrett, Board Chairman Martin J. Oberman, Board Vice Chairman and NGCC Co-Chair Karen J. Hedlund, and Board Members Patrick J. Fuchs, Michelle A. Schultz, and Robert E. Primus; reports by member groups on expectations for the upcoming harvest, domestic and foreign markets, the supply of rail cars, and rail service; and market and industry updates. The full agenda will be posted on the Board's website at *https://prod.stb.gov/resources/stakeholder-committees/grain-car-council.*

The meeting will be conducted pursuant to the Federal Advisory Committee Act, 5 U.S.C. app. 2; Federal Advisory Committee Management, 41 CFR. part 102–3; the NGCC charter; and Board procedures.

If you require an accommodation under the Americans with Disabilities Act for this meeting, please call (202) 245–0245.

Public Attendance: This meeting is physically open to the public on a space-available first come first serve basis. The meeting is also open to the public via Zoom. For login details, please contact Alan Cassiday, Designated Federal Officer for the NGCC, at *alan.cassiday@stb.gov.*

Public Comments: Members of the public may submit written comments to the NGCC at any time. Comments should be addressed to Alan Cassiday at *alan.cassiday@stb.gov*. Any further communications about this meeting will be announced through the Board's website, *www.stb.gov.*

Decided: July 26, 2023.

By the Board, Mai Dinh, Director, Office of Proceedings.

Stefan Rice,

Clearance Clerk.

[FR Doc. 2023–16187 Filed 7–28–23; 8:45 am]

BILLING CODE 4915–01–P

FEDERAL REGISTER

Vol. 88 Monday,

No. 145 July 31, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, et al.

45 CFR Part 180

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 416, 419, 424, 485, 488, 489

Office of the Secretary

45 CFR Part 180

[CMS–1786–P]

RIN 0938–AV09

Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Payment for Intensive Outpatient Services in Rural Health Clinics, Federally Qualified Health Centers, and Opioid Treatment Programs; Hospital Price Transparency; Changes to Community Mental Health Centers Conditions of Participation, Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor; Rural Emergency Hospital Conditions of Participation Technical Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for calendar year 2024 based on our continuing experience with these systems. In this proposed rule, we describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment system. This proposed rule also would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and the Rural Emergency Hospital Quality Reporting (REHQR) Program. This proposed rule would also establish payment for certain intensive outpatient services under Medicare, beginning January 1, 2024. In addition, this proposed rule would update and refine requirements for hospitals to make public their standard charge information and enforcement of hospital price transparency. We also propose to codify provisions of the Consolidated Appropriations Act, 2023, in Community Mental Health Centers Conditions of Participation (CoPs). We propose to revise the personnel qualifications of Mental Health Counselors and add personnel qualifications for Marriage and Family Therapists in the CMHC CoPs. We also seek comment on separate payment under the Inpatient Prospective Payment System (IPPS) for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. Finally, we propose to address any future revisions to the IPPS Medicare Code Editor (MCE), including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. Additionally, we propose a technical correction to the Rural Emergency Hospital Conditions of Participation.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 11, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1786–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–1786–P, P.O. Box 8010, Baltimore, MD 21244–1810.

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–1786–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:

Elise Barringer, *Elise.Barringer@cms.hhs.gov* or 410–786–9222.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center (ASC) Payment System, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov* or Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *marsha.hertzberg@cms.hhs.gov*.

Biosimilars Packaging Exception, contact Gil Ngan via email at *gil.ngan@cms.hhs.gov*.

Blood and Blood Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Chuck Braver via email at *Chuck.Braver@cms.hhs.gov*.

Community Mental Health Centers (CMHC) Conditions of Participation, contact Mary Rossi-Coajou via email at *Mary.RossiCoajou@cms.hhs.gov* or Cara Meyer via email at *Cara.Meyer@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health), via email at Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

Comprehensive APCs (C–APCs), contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov*.

COVID–19 Final Rules, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email *Kimberly.Go@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Janis Grady via email *Janis.Grady@cms.hhs.gov*.

Hospital Outpatient Visits (Emergency Department Visits and Critical Care Visits), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Hospital Price Transparency (HPT), contact Terri Postma via email at *PriceTransparencyHospitalCharges@cms.hhs.gov*.

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Inpatient Prospective Payment System (IPPS) Medicare Code Editor, contact Mady Hue via email at *Marilu.Hue@cms.hhs.gov*.

Mental Health Services Furnished Remotely by Hospital Staff to

Beneficiaries in Their Homes, contact Emily Yoder via email at *Emily.Yoder@cms.hhs.gov*.

Method to Control Unnecessary Increases in the Volume of Clinic Visit Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Opioid Treatment Program (OTP) Intensive Outpatient Services (IOP) contact Lindsey Baldwin via email at *Lindsey.Baldwin@cms.hhs.gov* and Ariana Pitcher at *Ariana.Pitcher@cms.hhs.gov*.

OPPS Brachytherapy, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at *Erick.Chuang@cms.hhs.gov*, or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*, or Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

OPPS Dental Policy, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*, or Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*, or Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Au'Sha Washington via email at *Ausha.Washington@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Mitali Dayal via email at *Mitali.Dayal2@cms.hhs.gov* or Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov*.

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Request for Public Comments on Potential Payment under the IPPS for Establishing and Maintaining Access to Essential Medicines, contact *DAC@cms.hhs.gov*.

Rural Emergency Hospital Conditions of Participation, contact Kianna Banks via email *Kianna.Banks@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program measures, contact Melissa Hager via email *Melissa.Hager@cms.hhs.gov*.

Rural Health Clinic (RHC) and Federally Qualified Health Center (FQHC) Intensive Outpatient Services (IOP), contact Michele Franklin via email at *Michele.Franklin@cms.hhs.gov*.

Separate Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Skin Substitutes, contact Josh McFeeters via email at *Joshua.McFeeters@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov*.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov*.

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* 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.

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the CY 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

The Addenda relating to the ASC payment system are available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.

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 2021 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

Table of Contents

I. Executive Summary of This Document
II. Proposed Updates Affecting OPPS Payments
A. Recalibration of APC Relative Payment Weights
B. Conversion Factor Update
C. Proposed Wage Index Changes
D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)
E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2024
F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2024
G. Proposed Hospital Outpatient Outlier Payments
H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment
I. Proposed Beneficiary Copayments
III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies
A. Proposed OPPS Treatment of New and Revised HCPCS Codes
B. Proposed OPPS Changes—Variations Within APCs
C. Proposed New Technology APCs
D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs
E. Proposed APC-Specific Policies
IV. Proposed OPPS Payment for Devices
A. Proposed Pass-Through Payment for Devices
B. Proposed Device-Intensive Procedures

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals
A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals
B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status
C. Requirement in the Physician Fee Schedule CY 2024 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs
VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices
A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment
B. Proposed Estimate of Pass-Through Spending for CY 2024
VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services
VIII. Payment for Partial Hospitalization and Intensive Outpatient Services
A. Partial Hospitalization
B. Intensive Outpatient Program Services
C. Coding and Billing for PHP and IOP Services Under the OPPS
D. Proposed Payment Rate Methodology for PHP and IOP
E. Proposed Outlier Policy for CMHCs
F. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)
G. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)
H. Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital
IX. Services That Will Be Paid Only as Inpatient Services
A. Background
B. Changes to the Inpatient Only (IPO) List
C. Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204
X. Proposed Nonrecurring Policy Changes
A. Supervision by Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation and Pulmonary Rehabilitation Services Furnished to Outpatients
B. Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital
C. OPPS Payment for Specimen Collection for COVID–19 Tests
D. Remote Services
E. OPPS Payment for Dental Services
F. Use of Claims and Cost Report Data for CY 2024 OPPS and ASC Payment System Ratesetting Due to the PHE
G. Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities
XI. Proposed CY 2024 OPPS Payment Status and Comment Indicators
A. Proposed CY 2024 OPPS Payment Status Indicator Definitions
B. Proposed CY 2024 Comment Indicator Definitions
XII. MedPAC Recommendations
A. OPPS Payment Rates Update
B. Medicare Safety Net Index
C. ASC Cost Data
XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System
A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System
B. Proposed ASC Treatment of New and Revised Codes
C. Payment Policies Under the ASC Payment System
D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists
E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices
F. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief Under the OPPS and ASC Payment System
G. Proposed New Technology Intraocular Lenses (NTIOLs)
H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor
XIV. Hospital Outpatient Quality Reporting (OQR) Program Requirements, Proposals, and Requests for Comment
A. Background
B. Hospital OQR Program Quality Measures
C. Hospital OQR Program Quality Measure Topics for Potential Future Consideration
D. Administrative Requirements
E. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program
F. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2024 Payment Determination
XV. Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program
A. Background
B. ASCQR Program Quality Measure
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the ASCQR Program
E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements
XVI. Proposed Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program
A. Background
B. REHQR Program Quality Measures
C. Administrative Requirements
D. Form, Manner, and Timing of Data Submitted for the REHQR Program
XVII. Changes to Community Mental Health Center (CMHC) Conditions of Participation (CoPs)
A. Background and Statutory Authority
B. Provisions of the Proposed Rule
XVIII. Proposed Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges
A. Introduction and Overview
B. Proposal To Modify the Requirements for Making Public Hospital Standard Charges at 45 CFR 180.50
C. Proposals To Improve and Enhance Enforcement
D. Seeking Comment on Consumer-Friendly Displays and Alignment With Transparency in Coverage and No Surprises Act
XIX. Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor
XX. Proposed Technical Edits for REH Conditions of Participation
XXI. Rural Emergency Hospitals (REHs): Proposal Regarding Payment For Rural Emergency Hospitals (REHs)
A. Background on Rural Emergency Hospitals
B. REH Payment Methodology
C. Background on the IHS Outpatient All-Inclusive Rate (AIR) for Tribal and IHS Hospitals
D. Proposal To Pay IHS and Tribal Hospitals That Convert to an REH Under the AIR
E. Exclusion of REHs From the OPPS
XXII. Request for Public Comments on Potential Payment Under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines
A. Overview
B. Establishing and Maintaining a Buffer Stock of Essential Medicines
C. Potential Separate Payment Under IPPS and OPPS for Establishing and Maintaining Access to a Buffer Stock Essential Medicines
D. Comment Solicitation on Additional Considerations
XXIII. Files Available to the Public via the internet
XXIV. Collection of Information Requirements
A. ICRs Related to Proposed Intensive Outpatient Physician Certification Requirements
B. ICRs Related to the Hospital OQR Program
C. ICRs Related to the ASCQR Program
D. ICRs Related to the REHQR Program
E. ICRs Related to Conditions of Participation (CoPs): Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)
F. ICR's Related to Conditions of Participation (CoPs): Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)
G. ICR's Related to Conditions of Participation (CoPs): Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)
H. ICRs Related to Hospital Price Transparency
XXV. Response to Comments
XXVI. Economic Analyses
A. Statement of Need
B. Overall Impact of Provisions of This Proposed Rule
C. Detailed Economic Analyses
D. Regulatory Review Cost Estimation
E. Regulatory Flexibility Act (RFA) Analysis

F. Unfunded Mandates Reform Act Analysis
G. Federalism
H. Conclusion

I. Summary and Background

A. Executive Summary of This Document

1. Purpose

In this proposed rule, we propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2024. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments that take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update and refine the requirements for the Hospital Outpatient Quality Reporting (OQR) Program, the ASC Quality Reporting (ASCQR) Program, and Rural Emergency Hospital Quality Reporting (REHQR) Program. In addition, this proposed rule would establish payment for intensive outpatient services under Medicare, beginning January 1, 2024. This proposed rule would also update and refine the requirements for hospitals to make public their standard charges and CMS enforcement of hospital price transparency regulations. In addition, this proposed rulemaking would also update the Community Mental Health Center (CMHC) Conditions of Participation (CoPs). We propose to revise the personnel qualifications of Mental Health Counselor's (MHCs) and add personnel qualifications for Marriage and Family Therapists (MFTs) in the CMHC CoP. Finally, we propose to remove discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking. Additionally, we propose a technical correction to the Rural Emergency Hospital (REH) CoPs under the standard for the designation and certification of REHs.

2. Summary of the Major Provisions

- *OPPS Update:* For 2024, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.8 percent. This proposed increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.0 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.2 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2024 would be approximately $88.6 billion, an increase of approximately $6.0 billion compared to estimated CY 2023 OPPS payments.

We propose to continue to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services.

- *Data used in Proposed CY 2024 OPPS/ASC Ratesetting:* To set proposed OPPS and ASC payment rates, we normally use the most updated claims and cost report data available. The best available claims data is the most recent set of data which would be from 2 years prior to the calendar year that is the subject of rulemaking. Cost report data usually lags the claims data by a year and we believe that using the most updated cost report extract available from the Healthcare Cost Report Information System (HCRIS) is appropriate for CY 2024 OPPS ratesetting. Therefore, we propose to resume our typical data process of using the most updated cost reports and claims data available for CY 2024 OPPS ratesetting.
- *Partial Hospitalization Update:* For CY 2024, we propose changes to our methodology used to calculate the Community Mental Health Center (CMHC) and hospital-based PHP (HB PHP) geometric mean per diem costs, as well as proposing changes to expand PHP payment from two APCs to four APCs.
- *Proposed Medicare Payment for Intensive Outpatient Programs:* Beginning in CY 2024, we propose to establish payment for intensive outpatient programs (IOPs) under Medicare. We propose the scope of benefits, physician certification requirements, coding and billing, and payment rates under the IOP benefit. IOP services may be furnished in hospital outpatient departments, community mental health centers (CMHCs), federally qualified health centers (FQHC), and rural health clinics (RHC). We also propose to establish payment for intensive outpatient services provided by opioid treatment programs (OTPs) under the existing OTP benefit.
- *Changes to the Inpatient Only (IPO) List:* For 2024, we are not proposing to remove any services from the IPO list.
- 340B-*Acquired Drugs:* For CY 2024, we propose to continue to apply the default rate, generally average sales price (ASP) plus 6 percent, to 340B acquired drugs and biologicals. Therefore, drugs and biologicals acquired under the 340B program would be paid at the same payment rate as those drugs and biologicals not acquired under the 340B program.
- *Biosimilar Packaging Exception:* For CY 2024, we propose to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid. In addition, if a reference product's per-day cost falls below the threshold packaging policy, we propose that all the biosimilars related to the reference product would be similarly packaged.
- *Proposal to Pay IHS and Tribal Hospitals that Convert to a Rural Emergency Hospital (REH) Under the IHS All-Inclusive Rate (AIR):* For CY 2024, we propose that IHS and tribal hospitals that convert to an REH be paid for hospital outpatient services under the same all-inclusive rate that would otherwise apply if these services were performed by an IHS or tribal hospital that is not an REH. We also propose that IHS and tribal hospitals that convert to an REH would receive the REH monthly facility payment consistent with how this payment is applied to REHs that are not tribally or IHS operated.
- *Device Pass-Through Payment Applications:* For CY 2024, we received 6 applications for device pass-through payments. We solicit public comment on these applications and will make final determinations on these applications in the CY 2024 OPPS/ASC final rule with comment period.

• *Cancer Hospital Payment Adjustment:* For CY 2024, we propose to continue providing additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. In light of the PHE impact on claims and cost data used to calculate the target PCR, we have maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. In this proposed rule, we propose to reduce the target PCR by 1.0 percentage point each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For CY 2024, we propose to use a target PCR of 0.88 to determine the CY 2024 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments will be the additional payments needed to result in a PCR equal to 0.88 for each cancer hospital.

• *ASC Payment Update:* For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID–19 PHE on healthcare utilization, we propose to extend our policy to update the ASC payment system using the hospital market basket update an additional two years—through CYs 2024 and 2025. Using the hospital market basket methodology, for CY 2024, we propose to increase payment rates under the ASC payment system by 2.8 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.2 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2024 will be approximately $6.0 billion, an increase of approximately $170 million compared to estimated CY 2023 Medicare payments.

• *Changes to the List of ASC Covered Surgical Procedures:* For CY 2024, we propose to add 26 dental surgical procedures to the ASC covered procedures list (CPL) based upon existing criteria at § 416.166.

• *Hospital Outpatient Quality Reporting (OQR) Program:* For the Hospital OQR Program measure set, we propose to: (1) remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/2026 payment determination; (2) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (3) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (4) modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (5) re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Procedures measure beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (6) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) beginning with the voluntary CYs 2025 and 2026 reporting periods, and mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (7) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (8) amend multiple codified regulations to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants. We are also requesting public comment on: (1) patient and workforce safety (including sepsis); (2) behavioral health (including suicide prevention); and (3) telehealth as potential future measurement topic areas in the Hospital OQR Program.

• *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* For the ASCQR Program measure set, we propose to: (1) modify the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure beginning with the CY 2024 Reporting Period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (5) adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) beginning with the voluntary CYs 2025 and 2026 reporting periods, and mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; and (6) amend multiple codified regulations to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

• *Rural Emergency Hospital Quality Reporting (REHQR) Program:* For the REHQR Program, we propose to: (1) codify the statutory authority for the REHQR Program; (2) adopt and codify policies related to measure retention, measure removal, and measure modification; (3) adopt one chart-abstracted measure and three claims-based measures for the REHQR Program measure set and establish related reporting requirements beginning with the CY 2024 reporting period; (4) adopt and codify policies related to public reporting of data; (5) codify foundational requirements related to REHQR Program participation; (6) adopt and codify policies related to the form, manner, and timing of data submission under the REHQR Program; (7) adopt and codify a review and corrections period for submitted data; and (8) adopt and codify an Extraordinary Circumstances Exception (ECE) process for data submission requirements. We are also requesting comment on the following potential measures and approaches for implementing quality reporting under the REHQR Program: (1) electronic clinical quality measures (eCQMs); (2) care coordination

measures; and (3) a tiered quality measure approach.

• *Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes:* For CY 2024, we propose technical refinements to the existing coding for remote mental health services to allow for multiple units to be billed daily. We also propose to create a new, untimed code to describe group psychotherapy. Finally, we propose to delay any in-person visit requirements until the end of CY 2024.

Proposed OPPS Payment for Dental Services: For CY 2024, we propose to assign 229 HCPCS codes describing dental services to various clinical APCs to align with Medicare payment provisions regarding dental services in the CY 2023 PFS final rule.

Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities: We are seeking comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribally-owned facilities.

• *Supervision by Nurse Practitioners, Physician Assistants and Clinical Nurse Specialists of Cardiac, Intensive Cardiac and Pulmonary Rehabilitation Services Furnished to Outpatients:* For CY 2024, to comply with section 51008 of the Bipartisan Budget Act of 2018 and to ensure consistency with proposed revisions to § 410.47 and § 410.49 in the CY 2024 PFS proposed rule, we propose to revise § 410.27(a)(1)(iv)(B)(1) to expand the practitioners who may supervise cardiac rehabilitation (CR), intensive cardiac rehabilitation (ICR), and pulmonary rehabilitation (PR) services to include nurse practitioners (NPs), physician assistants (PAs), and clinical nurse specialists (CNSs). We also propose to allow for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. *Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital:* For CY 2024, to address an unintended reimbursement disparity created by application of the off-campus, non-excepted payment rate to intensive cardiac rehabilitation services (ICR), we propose to pay for ICR services furnished by an off-campus, non-excepted PBD of a hospital at 100 percent of the OPPS rate, which is the amount paid for these services under the PFS.

• *Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges:* We propose to amend several of our hospital price transparency (HPT) requirements in order to improve our monitoring and enforcement capabilities by way of improving access to, and the usability of, hospital standard charge information; reduce the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; align, where feasible, certain hospital price transparency requirements and processes with requirements and processes we have implemented in the Transparency in Coverage (TIC) initiative; and make other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Specifically, we propose to: (1) add definitions for ''CMS template'', ''consumer-friendly expected allowed charges'', ''encode'', and ''machine-readable file'' (MRF); (2) require hospitals to affirm the accuracy and completeness of data in their MRF; (3) revise and expand the data elements hospitals must include in the MRF; (4) require hospitals to conform to a CMS template layout and other technical specifications for encoding standard charge information in the MRF; (5) require hospitals to establish and maintain a txt file and footer as specified by CMS; and (6) revise our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

• *Community Mental Health Center (CMHC) Conditions of Participation (CoPs):* We propose to update the CMHC CoPs to implement the provisions of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238) by establishing coverage of intensive outpatient services (IOP) in CMHCs. The CAA, 2023 also established a new Medicare benefit category for services furnished and directly billed by Mental Health Counselors (MHCs) and Marriage and Family Therapists (MFTs). We propose to revise the personnel qualifications of MHCs and add personnel qualifications for MFTs in the CMHC CoPs.

• *Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor:* Consistent with the process that is used for updates to the Integrated Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, we propose to remove discussion of the IPPS Medicare Code Editor (MCE) from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs.

• *Request for Public Comments on Potential Payment under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines:* We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. An adjustment under OPPS could be considered for future years.

• *Rural Emergency Hospital (REH) Conditions of Participation (CoPs):* We propose a technical correction to the REH CoPs under the standard for the ''Designation and certification of REHs.

3. Summary of Costs and Benefits

In section XXVI of this proposed rule, we set forth a detailed analysis of the regulatory and federalism impacts that the changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of all OPPS Changes

Table 100 in section XXVI.C of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2024 compared to all estimated OPPS payments in CY 2023. We estimate that the proposed policies in this proposed rule would result in a 2.9 percent overall increase in OPPS payments to providers. We estimate that total OPPS payments for CY 2024, including beneficiary cost-sharing, to the approximately 3,600 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $1.9 billion compared to CY 2023 payments, excluding our estimated changes in enrollment, utilization, and case-mix. We estimated the isolated impact of our

OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning in CY 2024, they will also be paid for new intensive outpatient program (IOP) services under the OPPS. Continuing the provider-specific structure we adopted beginning in CY 2011, and basing payment fully on the type of provider furnishing the service, we estimate a 5.8 percent increase in CY 2024 payments to CMHCs relative to their CY 2023 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2024 IPPS proposed rule wage indexes would result in no change for urban hospitals under the OPPS and a 1.4 percent increase for rural hospitals. These wage indexes include the continued implementation of the Office of Management and Budget (OMB) labor market area delineations based on 2010 Decennial Census data, with updates, as discussed in section II.C of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

We are implementing the reduction to the cancer hospital payment adjustment for CY 2024 required by section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act, and the proposed target payment-to-cost ratio (PCR) for CY 2024 cancer hospital adjustment of 0.89. However, as Section 16002 requires that we reduce the target PCR by 0.01, that brings the proposed target PCR to 0.88 instead. This is 0.01 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was previously held at the pre-PHE target.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2024 OPPS/ASC, we propose an OPD fee schedule increase factor of 2.8 percent and applying that proposed increase factor to the conversion factor for CY 2024. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 2.8 percent and that rural hospitals would experience an increase in payments of 4.4 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals would experience an increase in payments of 3.5 percent, minor teaching hospitals would experience an increase in payments of 3.0 percent, and major teaching hospitals would experience an increase in payments of 2.4 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 3.0 percent in payments, while hospitals with government ownership would experience an increase of 2.8 percent in payments. We estimate that hospitals with proprietary ownership would experience an increase of 3.4 percent in payments.

e. Impacts of the Proposed ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the CY 2024 payment rates, compared to estimated CY 2023 payment rates, generally ranges between a decrease of 6 percent and an increase of 7 percent, depending on the service, with some exceptions. We estimate the impact of applying the proposed inpatient hospital market basket update to ASC payment rates would increase payments by $170 million under the ASC payment system in CY 2024.

f. Impacts of Hospital Price Transparency

We propose to enhance automated access to hospital MRFs and aggregation and use of MRF data are estimated to increase burden on hospitals, including a one-time mean of $2,787 per hospital, and a total national cost of $19,784,539 ($2,787 × 7,098 hospitals). The cost estimate reflects estimated costs ranging from $1,274 and $4,181 per hospital, and a total national cost ranging from $9,040,620 to $29,676,809. As discussed in detail in section XXVI of this proposed rule, we believe that the benefits to the public (and to hospitals themselves) outweigh the burden imposed on hospitals.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA–TRHCA) (Pub. L. 109–432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110–173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111–148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111–309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112–78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112–96), enacted on February 22, 2012; the American Taxpayer Relief Act of 2012 (Pub. L. 112–240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113–93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114–10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114–74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114–113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–

141), enacted on March 23, 2018; the Substance Use Disorder- Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115–271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116–136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117–169), enacted on August 16, 2022; and Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–238), enacted December 29, 2022.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the ''2 times rule''). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. Section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as ''transitional pass-through payments,'' for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico; and
- Indian Health Service (IHS) hospitals.

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Public Law 106–113, and redesignated by section 202(a)(2) of Public Law 106–113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and

advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel—

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2022, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 22, 2022. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2018, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (83 FR 3715). CMS is currently accepting nominations at: *https://mearis.cms.gov*.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made;
- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and
- Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 22, 2022, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *https://facadatabase.gov*.

F. Public Comments Received on the CY 2023 OPPS/ASC Final Rule With Comment Period

We received approximately 12 timely pieces of correspondence on the CY 2023 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 4, 2022 (87 FR 71748). In-scope comments related to the interim APC assignments and/or status indicators of new or replacement Level II HCPCS codes (identified with comment indicator ''NI'' in OPPS Addendum B, ASC Addendum AA, and ASC Addendum BB to that final rule).

II. Proposed Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000 OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000 for each APC group.

For the CY 2024 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2024, and before January 1, 2025 (CY 2024), using the same basic methodology that we described in the CY 2023 OPPS/ASC final rule with comment period (86 FR 63466), using CY 2022 claims data. That is, we propose to recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights. For the purpose of recalibrating the proposed APC relative payment weights for CY 2024, we began with approximately 180 million final action claims (claims for which all

disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2022, and before January 1, 2023, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 93 million final action claims to develop the proposed CY 2024 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

Addendum N to this proposed rule (which is available via the internet on the CMS website at: *http://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) includes the proposed list of bypass codes for CY 2024. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2022 and, therefore, includes codes that were in effect in CY 2022 and used for billing. We propose to retain deleted bypass codes on the proposed CY 2024 bypass list because these codes existed in CY 2022 and were covered OPD services in that period, and CY 2022 claims data were used to calculate proposed CY 2024 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more ''pseudo'' single procedure claims for ratesetting purposes. ''Overlap bypass codes'' that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to the proposed rule. HCPCS codes that we propose to add for CY 2024 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2024, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2024 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2022 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2021. For the proposed CY 2024 OPPS payment rates, we used the set of claims processed during CY 2022. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2022 (the year of claims data we used to calculate the proposed CY 2024 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2022 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

In the CY 2023 OPPS/ASC final rule with comment period, a few commenters recommended that we revise our revenue code-to-cost center crosswalk to provide consistency with the NUBC definitions and to improve the accuracy of cost data for OPPS ratesetting with respect to chimeric antigen receptor therapy (CAR–T) administration services (87 FR 71758). In that final rule with comment period, we stated that we intend to explore the implications of this recommendation further and may consider such changes in future rulemaking. For this CY 2024 OPPS/ASC proposed rule, we explored the impacts of the commenters' recommendation from the CY 2023 OPPS/ASC final rule with comment period that we assign primary cost centers to certain CAR–T-related revenue codes that were not previously assigned cost centers. Specifically, for this CY 2024 OPPS/ASC proposed rule, we explored the commenter's recommendations regarding changes to the revenue code-to-cost center crosswalk, which included:

- Revising revenue codes 0870 (Cell/Gene Therapy General Classification) and 0871 (Cell Collection) to be mapped to a primary cost center of 9000 (Clinic);
- Revising revenue codes 0872 (Specialized Biologic Processing and Storage—Prior to Transport) and 0873 (Storage and Processing After Receipt of Cells from Manufacturer) to be mapped to a primary cost center of 3350 (Hematology);
- Revising revenue codes 0874 (Infusion of Modified Cells) and 0875 (Injection of Modified Cells) to be mapped to a primary cost center of 6400 (Intravenous Therapy), and;
- Revising revenue codes 0891 (Special Processed Drugs—FDA Approved Cell Therapy) and 0892 (Special Processed Drugs—FDA Approved Gene Therapy) to be mapped to a primary cost center of 7300 (Drugs Charged to Patients).

After reviewing the impact of these crosswalk revisions on our proposed CY 2024 OPPS APC geometric mean costs, we only observed an increase in the geometric mean cost of CPT code 0540T (Chimeric antigen receptor t-cell (car-t) therapy; car-t cell administration, autologous)—from $148.31 to $294.17 for this proposed rule—as a result of the revenue code for CPT code 0540T being assigned to a new cost center and the new corresponding cost-to-charge ratio. We did not observe any significant impact on APC geometric mean costs or payment as a result of these revisions. We believe these revisions would provide greater consistency with the NUBC definitions (which already adopted these revenue code revisions) and more accurately account for the costs of CAR–T administration services under the OPPS. Therefore, for CY 2024 and subsequent years, we propose to adopt the aforementioned revisions to revenue codes 0870, 0871 0872, 0873, 0874, 0875, 0891, and 0892 in our revenue code-to-cost center crosswalk.

We solicit comment on our proposed changes to the revenue code-to-cost center crosswalk for CY 2024. In accordance with our longstanding policy, similar to our finalized policy for CY 2023 OPPS ratesetting, we propose to calculate CCRs for the standard cost centers—cost centers with a predefined label—and nonstandard cost centers—cost centers defined by a hospital—accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including them in OPPS ratesetting. For CY 2024, we propose not to include the nonstandard cost centers

reported in this way in the OPPS ratesetting database construction.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2024. The Hospital OPPS page on the CMS website on which this proposed rule is posted (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*) provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*, includes information about obtaining the ''OPPS Limited Data Set,'' which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including ICD–10–CM diagnosis codes and revenue code payment amounts. This file is derived from the CY 2022 claims that are used to calculate the proposed payment rates for this proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a through II.A.2.c of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2024 shown in Addenda A and B to this proposed rule (which are available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*). We refer readers to section II.A.4 of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier ''PN,'' which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier ''PN'' from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2024 OPPS, we propose to continue to remove claim lines with modifier ''PN'' from the ratesetting process.

For details of the claims accounting process used in this CY 2024 OPPS/ASC proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

a. Proposed Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs.

We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology, which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

Because this proposed hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*) for the proposed CY 2024 payment rates for blood and blood products (which are generally identified with status indicator ''R'').

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- the CY 2005 OPPS proposed rule (69 FR 50524 through 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and

• the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 through 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C–APC. We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy—cancer treatment through solid source radioactive implants—consisting of a seed or seeds (or radioactive source) (''brachytherapy sources'') separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 through 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for a number of reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services. This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for the vast majority of items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2024, except where otherwise indicated, we propose to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates for brachytherapy sources because CY 2022 is the year of data we propose to use to set the proposed payment rates for most other items and services that would be paid under the CY 2024 OPPS. We proposed this methodology for CY 2024 and subsequent years. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2 of this proposed rule. We also propose for CY 2024 and subsequent years, to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). For CY 2024 and subsequent years, we propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2024 and subsequent years, we also propose to continue the policy we first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, based on the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110–275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2024 payment rates for brachytherapy sources are included on Addendum B to this proposed rule (which is available via the internet on the CMS website) and identified with status indicator ''U.''

For CY 2018, we assigned status indicator ''U'' (Brachytherapy Sources, Paid under OPPS; separate APC payment) to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm² for the brachytherapy source's APC—APC 2648 (Brachytx planar, p-103). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm² for APC 2648 (Brachytx planar, p-103). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm². In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm² may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, and 87 FR 71760 through 71761), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm² for HCPCS code C2645 for CY 2021, for CY 2022, and for CY 2023.

After reviewing CY 2022 claims data available for this proposed rule, we observed three claims that reported HCPCS code C2645. Each claim reported one unit of HCPCS code C2645 and the geometric mean unit cost from these three claims yielded $168.67. We are unable to use these claims for ratesetting purposes given the reporting of only one unit per claim and the high geometric mean cost. Therefore, we propose to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2023 payment rate of $4.69 per mm² for HCPCS code C2645, which is assigned to APC 2648 (Brachytx planar, p-103), for CY 2024.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under Section 1833(t)(2)(E) of the Act in the case of APC 2648 (Brachytx planar, p-103), for which HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) is the only code assigned as discussed previously in this section.

For CY 2024, we propose to designate five brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as a Low Volume APC. For more information on the brachytherapy APCs we propose to designate as Low Volume APCs, see section III.D of this proposed rule.

We invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to *outpatientpps@cms.hhs.gov* or by mail to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C–APCs) for CY 2024

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014 but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C–APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C–APC policy (79 FR 66798 through 66810).

A C–APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C–APCs as a category broadly for OPPS payment and implemented 25 C–APCs beginning in CY 2015 (79 FR 66809 through 66810). We have gradually added new C–APCs since the policy was implemented beginning in CY 2015, with the number of C–APCs now totaling 70 (80 FR 70332; 81 FR 79584 through 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; and 87 FR 71769).

Under our C–APC policy, we designate a service described by a HCPCS code assigned to a C–APC as the primary service when the service is identified by OPPS status indicator ''J1''. When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as ''adjunctive services'') and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C–APC policy under the OPPS include services that are not covered OPD services, services that cannot by statute be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 through 66801). A list of services excluded from the C–APC policy is included in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*). If a service does not appear on this list of excluded services, payment for it will be packaged into the payment for the primary C–APC service when it appears on an outpatient claim with a primary C–APC service.

The C–APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C–APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator ''J1,'' [1] excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator ''J1'' are assigned to C–APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C–APC payment methodology to qualifying extended assessment and management encounters through the ''Comprehensive Observation Services'' C–APC (C–APC 8011). Services within this APC are assigned status indicator ''J2.'' [2] Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator ''T'';
- Contains 8 or more units of services described by HCPCS code G0378

[1] Status indicator ''J1'' denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2024 Addendum D1.

[2] Status indicator ''J2'' denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2024 Addendum D1.

(Hospital observation services, per hour);

• Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

• Does not contain services described by a HCPCS code to which we have assigned status indicator ''J1.''

The assignment of status indicator ''J2'' to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C–APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523) for further instructions on reporting these services in the context of a C–APC service.

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868 through 74869, and 74909, and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.[3]

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator ''J1'' as a single ''J1'' unit procedure claim (78 FR 74871 and 79 FR 66801). Line item charges for services included on the C–APC claim are converted to line item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator ''J1'' and later used to develop the geometric mean costs for the C–APC relative payment weights. (We note that we use the term ''comprehensive'' to describe the geometric mean cost of a claim reporting ''J1'' service(s) or the geometric mean cost of a C–APC, inclusive of all of the items and services included in the C–APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C–APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator ''J1'' according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator ''J1'' or units thereof, we identify one ''J1'' service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple ''J1'' procedure claims to the C–APC to which the service designated as the primary service is assigned. If the reported ''J1'' services on a claim map to different C–APCs, we designate the ''J1'' service assigned to the C–APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple ''J1'' services on a claim map to the same C–APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned

[3] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

to status indicator ''J1'' to the most appropriate C–APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and certain add-on codes (as described further below) from the originating C–APC (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2 of this proposed rule, in the originating C–APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator ''J1'' (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C–APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of ''J1'' services (or combinations of ''J1'' services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C–APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C–APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary ''J1'' service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2024, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator ''J1'' and any number of units of a single add-on code for the primary ''J1'' service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C–APC within the same clinical family of C–APCs. As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C–APC. We list the complexity adjustments for ''J1'' and add-on code combinations for CY 2024, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C–APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for the code combination described by complexity adjustment assignment 3320R, which is assigned to C–APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C–APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Exclusion of Procedures Assigned to New Technology APCs From the C–APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C–APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator ''J1,'' payment for the new technology service was typically packaged into the payment for the primary procedure. Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a ''J1'' service assigned to a C–APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator ''J2'' when they are included on a claim with a ''J2'' service (84 FR 61167).

(3) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified Drugs or Biologicals) From the C–APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the FDA and that does not yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C–APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 has been included in the C–APC payment when these products appear on a claim with a primary C–APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C–APC service is consistent with our C–APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It has been our position that the total payment for the C–APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we have determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C–APC service. In order to ensure payment for new drugs, biologicals, and radiopharmaceuticals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug, biological, or radiopharmaceutical described by HCPCS code C9399 from packaging when the drug, biological, or radiopharmaceutical is included on a claim with a ''J1'' service, which is the status indicator assigned to a C–APC, and a claim with a ''J2'' service, which is the status indicator assigned to comprehensive observation services. Please see Addendum J for the CY 2024 comprehensive APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI ''CY 2023 OPPS Payment Status and Comment Indicators'' to add a new definition to status indicator ''A'' to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The definition, found in Addendum D1, would ensure the MAC prices claims for drugs, biologicals or radiopharmaceuticals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug, biological, or radiopharmaceutical under the OPPS when it appears on the same claim as a primary C–APC service.

(4) Additional C–APCs for CY 2024

For CY 2024 and subsequent years, we propose to continue to apply the C–APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C–APC payment policy methodology and revisions. Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any standard APCs to C–APCs in CY 2024, but we are creating two new APCs that will both be C–APCs. Thus, we propose that the number of C–APCs for CY 2024 would be 72 C–APCs.

For this proposed rule, we propose to split the Level 2 Intraocular APC (APC 5492) into two and assign the higher cost procedures previously within this

APC to a new Level 3 Intraocular APC (APC 5493). The previous Level 3, Level 4, and Level 5 Intraocular APCs (APCs 5493, 5494, and 5495) will be renamed the Level 4, Level 5, and Level 6 Intraocular APC (APCs 5494, 5495, and 5496), respectively. We refer readers to section III.E of this proposed rule for more information regarding this proposal.

We also propose to add a new Level 2 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5342) to improve clinical and resource homogeneity in the Level 1 Abdominal/Peritoneal/Biliary and Related Procedures APC (APC 5341).

Table 1 lists the proposed C–APCs for CY 2024. All C–APCs are displayed in Addendum J to this proposed rule (which is available via the internet on the CMS website). Addendum J to this proposed rule also contains all the data related to the C–APC payment policy methodology, including the list of complexity adjustments and other information for CY 2024.

BILLING CODE 4120–01–P

TABLE 1: PROPOSED CY 2024 C-APCs

C-APC	CY 2024 APC Group Title	Clinical Family	New C-APC
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX	
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX	
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS	
5112	Level 2 Musculoskeletal Procedures	ORTHO	
5113	Level 3 Musculoskeletal Procedures	ORTHO	
5114	Level 4 Musculoskeletal Procedures	ORTHO	
5115	Level 5 Musculoskeletal Procedures	ORTHO	
5116	Level 6 Musculoskeletal Procedures	ORTHO	
5153	Level 3 Airway Endoscopy	AENDO	
5154	Level 4 Airway Endoscopy	AENDO	
5155	Level 5 Airway Endoscopy	AENDO	
5163	Level 3 ENT Procedures	ENTXX	
5164	Level 4 ENT Procedures	ENTXX	
5165	Level 5 ENT Procedures	ENTXX	
5166	Cochlear Implant Procedure	COCHL	
5182	Level 2 Vascular Procedures	VASCX	
5183	Level 3 Vascular Procedures	VASCX	
5184	Level 4 Vascular Procedures	VASCX	
5191	Level 1 Endovascular Procedures	EVASC	
5192	Level 2 Endovascular Procedures	EVASC	
5193	Level 3 Endovascular Procedures	EVASC	
5194	Level 4 Endovascular Procedures	EVASC	
5200	Implantation Wireless PA Pressure Monitor	WPMXX	
5211	Level 1 Electrophysiologic Procedures	EPHYS	
5212	Level 2 Electrophysiologic Procedures	EPHYS	
5213	Level 3 Electrophysiologic Procedures	EPHYS	
5222	Level 2 Pacemaker and Similar Procedures	AICDP	
5223	Level 3 Pacemaker and Similar Procedures	AICDP	
5224	Level 4 Pacemaker and Similar Procedures	AICDP	
5231	Level 1 ICD and Similar Procedures	AICDP	
5232	Level 2 ICD and Similar Procedures	AICDP	
5244	Level 4 Blood Product Exchange and Related Services	SCTXX	
5302	Level 2 Upper GI Procedures	GIXXX	
5303	Level 3 Upper GI Procedures	GIXXX	

C-APC	CY 2024 APC Group Title	Clinical Family	New C-APC
5313	Level 3 Lower GI Procedures	GIXXX	
5331	Complex GI Procedures	GIXXX	
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX	*
5361	Level 1 Laparoscopy and Related Services	LAPXX	
5362	Level 2 Laparoscopy and Related Services	LAPXX	
5372	Level 2 Urology and Related Services	UROXX	
5373	Level 3 Urology and Related Services	UROXX	
5374	Level 4 Urology and Related Services	UROXX	
5375	Level 5 Urology and Related Services	UROXX	
5376	Level 6 Urology and Related Services	UROXX	
5377	Level 7 Urology and Related Services	UROXX	
5378	Level 8 Urology and Related Services	UROXX	
5414	Level 4 Gynecologic Procedures	GYNXX	
5415	Level 5 Gynecologic Procedures	GYNXX	
5416	Level 6 Gynecologic Procedures	GYNXX	
5431	Level 1 Nerve Procedures	NERVE	
5432	Level 2 Nerve Procedures	NERVE	
5461	Level 1 Neurostimulator and Related Procedures	NSTIM	
5462	Level 2 Neurostimulator and Related Procedures	NSTIM	
5463	Level 3 Neurostimulator and Related Procedures	NSTIM	
5464	Level 4 Neurostimulator and Related Procedures	NSTIM	
5465	Level 5 Neurostimulator and Related Procedures	NSTIM	
5471	Implantation of Drug Infusion Device	PUMPS	
5491	Level 1 Intraocular Procedures	INEYE	
5492	Level 2 Intraocular Procedures	INEYE	
5493	Level 3 Intraocular Procedures	INEYE	
5494	Level 4 Intraocular Procedures	INEYE	
5495	Level 5 Intraocular Procedures	INEYE	
5496	Level 6 Intraocular Procedures	INEYE	*
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE	
5627	Level 7 Radiation Therapy	RADTX	
5881	Ancillary Outpatient Services When Patient Dies	N/A	
8011	Comprehensive Observation Services	N/A	

C-APC Clinical Family Descriptor Key:

AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

BILLING CODE 4120–01–C

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary, high quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241 through 59242 and 59246 through 52950) for more recent background.

(1) Mental Health Services Composite APC

We propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for more recent background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 through 33581 and 59246 through 59247, respectively), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate that will be paid for APC 5863, which is the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital will continue to be paid the payment rate for composite APC 8010. Under this policy, the Integrated OCE (I/OCE) will continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5863 for all of the specified mental health services furnished by the hospital on that single date of service. We continue to believe that the costs associated with administering a partial hospitalization program at a hospital represent the most resource intensive of all outpatient mental health services.

We propose that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for 3 partial hospitalization services provided in a day by a hospital, those specified mental health services would be paid

through composite APC 8010 for CY 2024. In addition, we propose to set the payment rate for composite APC 8010 at the same payment rate that we propose for APC 5863, which is a partial hospitalization per diem payment rate for 3 partial hospitalization services furnished in a day by a hospital, and that the hospital continue to be paid the proposed payment rate for composite APC 8010. While APC 5863 is no longer the maximum partial hospitalization per diem payment rate for a hospital, due to proposed APC 5864, which is 4 or more hospital-based PHP services per day, discussed in section VIII.B of this proposed rule, we believe it is still appropriate to apply the APC 5863 per diem payment amount as the upper limit on payment per day for individual OPPS mental health services. This is because the daily mental health cap would not be expected to reach a level of intensity beyond 3 services per day, as described by APC 5863. The PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received. We would not anticipate more than three services per patient on a given day, as patients needing additional services in one day would potentially require an inpatient admission., as described by APC 5863. Thus, setting the mental health cap at APC 5863, rather than the 4 service per day APC 5864, is more consistent with our longstanding policy, which has been for the 3 service per day APC. We note that the proposed CY 2024 payment amount for APC 5863 would be comparable to the CY 2023 payment amount for APC 5863, which is the PHP APC used to set the daily mental health cap for CY 2023.

However, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital, we are also soliciting comment on whether the next higher level APC, proposed APC 5864, which is for four hospital-based PHP services per day, would be appropriate to use as the daily mental health cap.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 2 below.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);
- APC 8006 (CT and CTA with Contrast Composite);
- APC 8007 (MRI and MRA without Contrast Composite); and
- APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the ''with contrast'' composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the ''with contrast'' composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2024, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2024, except where otherwise indicated, we propose to use the costs derived from CY 2022 claims data to set the proposed CY 2024 payment rates. Therefore, for CY 2024, the payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) are based on proposed geometric mean costs calculated from CY 2022 claims available for this proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same family on a single date of service). To calculate the proposed geometric mean costs, we have used the same methodology that we use to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as ''overlap bypass codes'' that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the internet on the CMS website) and are discussed in more detail in section II.A.1.b of this proposed rule.

For CY 2024, we were able to identify approximately 0.95 million ''single session'' claims out of an estimated 2.0 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 47.5 percent of all eligible claims, to calculate the proposed CY 2024 geometric mean costs for the multiple imaging composite APCs. Table 2 of this proposed rule lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC proposed geometric mean costs for CY 2024.

TABLE 2: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2024 APC 8004 (Ultrasound Composite)	**CY 2024 Approximate APC Geometric Mean Cost = $313.97**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma
76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2024 APC 8005 (CT and CTA without Contrast Composite)*	**CY 2024 Approximate APC Geometric Mean Cost = $229.30**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2024 APC 8006 (CT and CTA with Contrast Composite)	**CY 2024 Approximate APC Geometric Mean Cost = $434.54**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+

0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye
72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a "without contrast" CT or CTA procedure is performed during the same session as a "with contrast" CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2024 APC 8007 (MRI and MRA without Contrast Composite)*	**CY 2024 Approximate APC Geometric Mean Cost = $533.84**
0609T	Mrs disc pain acquisj data

70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral
77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2024 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2024 Approximate APC Geometric Mean Cost = $847.83**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye

72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd
C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr
* If a “without contrast” MRI or MRA procedure is performed during the same session as a “with contrast” MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.	

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery. Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payment because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Because packaging encourages efficiency and is an essential component of a prospective payment system, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Proposal and Comment Solicitation on Packaged Items and Services

For CY 2024, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2024, we do not propose any changes to the overall packaging policy previously discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

While we do not propose any changes to the overall packaging policy above, we solicit comments on potential modifications to our packaging policy as described in the following sections.

c. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively. Because the additional payments are required to begin on January 1, 2025, we will include our proposals to implement the CAA, 2023 section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We discuss section 4135 of CAA, 2023 at length in section XIII.F of this proposed rule, where we solicit comment on numerous aspects of this future policy. While we expect this policy to operate similarly in the ASC and HOPD settings, we welcome comment on whether there are any HOPD specific payment issues we should take into consideration as we plan to implement section 1833(t)(16)(G) of the Act for CY 2025.

d. Comment Solicitation on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

(i) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. As the products are packaged according to the policies in § 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure is packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages

hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

Diagnostic radiopharmaceuticals, which include contrast agents, stress agents, and other products, are one specific type of product that is policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties have raised concerns regarding policy packaging of diagnostic radiopharmaceuticals. In previous rulemaking (87 FR 71962 through 71963), commenters recommended that CMS always pay separately for diagnostic radiopharmaceuticals paid under the OPPS, not just when the products have pass-through payment status. Many of these commenters mentioned that pass-through payment status helps the diffusion of new diagnostic radiopharmaceuticals into the market. However, commenters believe the packaged payment rate is often inadequate after pass-through status expires, especially in cases where the diagnostic radiopharmaceutical is high-cost and has low utilization.

CMS has previously heard from interested parties regarding alternative payment methodologies, such as subjecting diagnostic radiopharmaceuticals to the drug packaging threshold and creating separate APC payments for diagnostic radiopharmaceuticals with a per-day cost greater than $500. Interested parties have also recommended that we analyze our nuclear medicine APC structure and consider establishing additional nuclear medicine APCs to more accurately reflect the costs of diagnostic radiopharmaceuticals. Historically, commenters opposed incorporating the cost of diagnostic radiopharmaceuticals into the associated nuclear medicine APC as the nuclear medicine APCs are sometimes paid at a lower rate than the payment rate for the diagnostic radiopharmaceutical itself when it has pass-through payment status (87 FR 71962 through 71963).

Importantly, commenters historically have also been concerned that packaging payment for precision diagnostic radiopharmaceuticals in the outpatient setting creates barriers to beneficiary access for safety net hospitals serving a high proportion of Medicare beneficiaries and hospitals serving underserved communities (87 FR 71962 through 71963). Commenters specified that certain populations, such as those with Alzheimer's disease, depend on the use of certain high-cost diagnostic radiopharmaceuticals. Commenters discussed difficulties enrolling hospitals in clinical studies due to OPPS packaging policies. Commenters also suggested that CMS pay separately under the OPPS specifically for radiopharmaceuticals that are used for Alzheimer's disease. Additionally, commenters have recommended that CMS continue to apply radiolabeled product edits to the nuclear medicine procedures to ensure that all packaged costs are included on nuclear medicine claims in order to establish appropriate payment rates in the future. Many of these comments and our responses have been discussed in rulemaking since the policy to package diagnostic radiopharmaceuticals was adopted. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71962 through 71963) for the most recent discussion of this subject.

We continue to believe that diagnostic radiopharmaceuticals are an integral component of many nuclear medicine and imaging procedures and charges associated with them should be reported on hospital claims to the extent they are used. Accordingly, the payment for the radiopharmaceuticals should be reflected within the payment for the primary procedure. We note that ratesetting uses the geometric mean of reported procedure costs based on data submitted to CMS from all hospitals paid under the OPPS to set the payment rate for the service. The costs that are calculated by Medicare reflect the average costs of items and services that are packaged into a primary procedure and will not necessarily equal the sum of the cost of the primary procedure and the average sales price of the specific items and services used in the procedure in each case. Furthermore, the costs are based on the reported costs submitted to Medicare by the hospitals and not the list price established by the manufacturer. Claims data that include the radiopharmaceutical packaged with the associated procedure reflect the combined cost of the procedure and the radiopharmaceutical used in the procedure.

As CMS has reiterated over the years, we believe these packaging policies are inherent principles of the OPPS and are essential to a prospective payment system. We are also committed to ensuring beneficiary access to diagnostic radiopharmaceuticals while also ensuring the availability of new and innovative diagnostic tools for Medicare beneficiaries. Therefore, we are seeking public comments on potential modifications to our packaging policy for diagnostic radiopharmaceuticals in order to ensure equitable payment and continued beneficiary access.

Depending on the comments we receive in response to this comment solicitation, we may adopt as final alternative payment mechanisms for radiopharmaceuticals for CY 2024 in the CY 2024 OPPS/ASC final rule with comment period.

(ii) Comment Solicitation on Potential Issues Caused by Current Payment of Diagnostic Radiopharmaceuticals Under the OPPS

We are soliciting comment on how the OPPS packaging policy for diagnostic radiopharmaceuticals has impacted beneficiary access, including whether there are specific patient populations or clinical disease states for whom this issue is especially critical. We seek information on specific cost-prohibitive diagnostic radiopharmaceuticals that commenters believe are superior to alternative diagnostic modalities. We are interested to learn the specific clinical scenarios that exist for which it is only clinically appropriate to use the more expensive diagnostic radiopharmaceutical, rather than a lower cost alternative, as well as what clinical scenarios exist in which the only diagnostic modality is a high-cost radiopharmaceutical. We are seeking information or evidence that these high-cost diagnostic radiopharmaceuticals have unique clinical value, and access has been negatively impacted by our packaging policy. We are also seeking information about whether commenters believe these high-cost and low-utilization diagnostic radiopharmaceuticals are being appropriately utilized according to their clinical treatment algorithm, meaning the stepwise procedures generally accepted by the medical community for diagnosis, or clinical practice guidelines.

We are also interested in learning more about whether there is a difference in outcomes for patients, or patient quality of care, based on the radiopharmaceutical used as well as whether there is a difference for hospitals, such as in terms of financial outcomes, based on the radiopharmaceutical that used.

(iii) Comment Solicitation on New Approaches to Payment of Diagnostic Radiopharmaceuticals Under the OPPS

In addition, we are soliciting comment on the following potential approaches that would enhance beneficiary access, while also maintaining the principles of the outpatient prospective payment system. These approaches include: (1) paying separately for diagnostic radiopharmaceuticals with per-day costs

above the OPPS drug packaging threshold of $140; (2) establishing a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold; (3) restructuring APCs, including by adding nuclear medicine APCs for services that utilize high-cost diagnostic radiopharmaceuticals; (4) creating specific payment policies for diagnostic radiopharmaceuticals used in clinical trials; and (5) adopting codes that incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals.

To expand upon the first listed option on which we solicit comments, we are specifically seeking comments about whether we should use our statutory authority for separately payable drugs, biologicals, and radiopharmaceuticals under 1833(t)(14)(A)(iii)(II) of the Act in order to pay separately for diagnostic radiopharmaceuticals and subject those diagnostic radiopharmaceuticals to the longstanding OPPS drug packaging threshold policy, proposed to be $140 for CY 2023. Or said another way, payment for diagnostic radiopharmaceuticals with per-day costs greater than $140 would not be packaged and would be paid separately based on available average sales price (ASP), wholesale acquisition cost (WAC), or average wholesale price (AWP) data with the applicable add-on. This would be similar to payment for therapeutic radiopharmaceuticals and other drugs and biologicals as discussed in section V.B. of this proposed rule. We believe this could be a reasonable first step as this threshold is well understood and known to commenters as therapeutic drugs, biologicals, and radiopharmaceuticals are currently paid separately if they have a calculated per-day cost above this threshold and are not policy-packaged. However, it is also our longstanding belief that diagnostic radiopharmaceuticals should have their payment packaged as they function as supplies during a diagnostic test or procedure and enable the provision of an independent service and are not themselves the primary therapeutic modality. We seek additional information from interested parties on this approach.

Regarding the second listed option, we seek comment on whether to pay separately for a diagnostic radiopharmaceutical with a specific per-day cost threshold that may be greater or less than the OPPS drug packaging threshold. Specifically, we are interested to learn why interested parties believe a threshold-based policy is important as well as interested parties' rationale for creating a threshold that would be different from the OPPS drug packaging threshold.

Regarding the third listed option, we have heard from some interested parties that they believe APC restructuring, including adding additional nuclear medicine APCs for services utilizing high-cost diagnostic radiopharmaceuticals, would be appropriate. We seek comment as to how these interested parties specifically envision operationalizing this approach and what advantage this approach would have for beneficiaries, hospitals, and CMS over other options.

For the fourth listed option, we recently became aware that some interested parties believe that CMS packaging policies could influence participation of beneficiaries and testing sites in clinical trials, particularly those studying Alzheimer's disease, and are interested to learn more about these concerns. While we believe there could be a multitude of reasons for difficulty in recruiting study sites and beneficiaries for clinical trials, including the COVID–19 PHE, we are requesting comment as to whether CMS should consider creating payment policies for diagnostic radiopharmaceuticals used in clinical trials. Specifically, we are interested to learn what commenters believe an appropriate payment mechanism would be for these diagnostic radiopharmaceuticals, whether there are certain disease states or categories of trials for which we should target our payment policies, ways in which this policy could help promote equitable recruitment and diverse participation, and the method by which CMS should determine which clinical trial diagnostic radiopharmaceuticals should be subject to this policy.

Finally, for approach five, we are seeking comment on new codes that CMS could adopt that may incorporate the disease state being diagnosed or a diagnostic indication of a particular class of diagnostic radiopharmaceuticals. CMS could create indication-specific coding to reflect the imaging procedure and the target of the imaging procedure. For example, CMS could create a code to represent a PET scan that detects a specific protein. If multiple diagnostic radiopharmaceuticals are available to use during this PET scan to detect this specific protein, then their payment would be packaged into the payment for this newly created code and reflected in the payment for this code. Therefore, if there is a specific clinical indication for which only very costly diagnostic radiopharmaceuticals are available, our data would appropriately reflect their utilization. Alternatively, if there is a specific clinical indication in which a wide variety of diagnostic radiopharmaceuticals can be used, all with varying costs, then our data would reflect this and our payment rates would not incentivize a higher-cost diagnostic radiopharmaceutical when there is a lower-cost, but clinically similar, diagnostic radiopharmaceutical alternative. This coding approach could be coupled with the restructuring of the nuclear medicine APC family. We believe this approach of more granular coding could allow for more specific data to be reported and thus more targeted and appropriate payment rates to be developed. This approach would also help to maintain the principles of a prospective payment system by maintaining current packaging policies as payment for the diagnostic radiopharmaceutical would continue to be packaged into the payment for the procedure in which the diagnostic radiopharmaceutical is used.

We also seek additional explanation from interested parties as to why they believe their suggested approach is the best policy approach to ensure beneficiary access to diagnostic radiopharmaceuticals and equitable payment for innovative and effective technologies. We welcome comment regarding ideas discussed in this section, discussed in prior rulemaking, or new ideas for payment for diagnostic radiopharmaceuticals in OPPS.

Finally, we are interested in hearing from stakeholders how the discussed policy modifications might impact our overarching goal of utilizing packaging policies to better align OPPS policies with that of a prospective payment system rather than a fee schedule. We would also like to know if making any of the policy changes discussed previously could have negative consequences for beneficiaries, such as unintentionally influencing clinical practice decisions, increasing beneficiary cost-sharing obligations, or inadvertently encouraging the use of higher-cost diagnostic radiopharmaceuticals over lower cost, but equally effective, diagnostic options.

We note that depending on the comments received, we may adopt as final one or more alternative payment mechanisms for radiopharmaceuticals for CY 2024.

4. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to

calculate relative payment weights under the OPPS. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71778 through 71780), we applied this policy and calculated the relative payment weights for each APC for CY 2023 that were shown in Addenda A and B of the CY 2023 OPPS/ASC final rule with comment period (which were made available via the internet on the CMS website) using the APC costs discussed in sections II.A.1 and II.A.2 of the CY 2023 OPPS/ASC final rule with comment period (87 FR 71757 through 71777). For CY 2024, as we did for CY 2023, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2024 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing any and all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For CY 2024, as we did for CY 2023, we propose to continue to standardize all of the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2024, as we did for CY 2023, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2024 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2023 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2024 unscaled relative payment weights.

For CY 2023, we multiplied the CY 2023 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2022 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services in order to calculate an estimated aggregate weight for the year. For CY 2024, we propose to apply the same process using the estimated CY 2024 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2023 estimated aggregate weight by the unscaled CY 2024 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*. Click on the link labeled ''CY 2024 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2024 NPRM OPPS Claims Accounting (PDF)''.

We propose to compare the estimated unscaled relative payment weights in CY 2024 to the estimated total relative payment weights in CY 2023 using CY 2022 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2024 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2024 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4529 to ensure that the proposed CY 2024 relative payment weights are scaled to be budget neutral. The proposed CY 2024 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1 and II.A.2 of this proposed rule.

Section 1833(t)(14) of the Act provides the payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2 of this proposed rule) is included in the budget neutrality calculations for the CY 2024 OPPS.

B. Proposed Conversion Factor Update

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD rate increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD rate increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges under section 1886(b)(3)(B)(iii) of the Act. In the FY 2024 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (88 FR 27004 through 27005), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2022 forecast, the proposed FY 2024 IPPS market basket percentage increase was 3.0 percent. We note that under our regular process for the CY 2024 OPPS/ASC final rule, we would use the market basket update for the FY 2024 IPPS/LTCH PPS final rule, which would be based on IHS Global, Inc.'s second quarter 2023 forecast of the FY 2024 IPPS market basket percentage increase. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2024 OPPS/ASC final rule OPD rate increase factor would reflect that updated forecast of the market basket percentage increase.

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be

reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment as 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 fiscal year, year, cost reporting period, or other annual period) (the ''productivity adjustment''). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment, and then revised this methodology, as discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49509). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021 release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. 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 total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* 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-Dataand-Systems/Statistics-Trends-andReports/MedicareProgram RatesStats/* MarketBasketResearch. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005), the proposed productivity adjustment for FY 2024 was 0.2 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2024 OPPS would be 0.2 percentage point. We also propose that if more recent data subsequently become available after the publication of this proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such updated data, if appropriate, to determine the CY 2024 market basket update and the productivity adjustment, which are components in calculating the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year, and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we propose for CY 2024 an OPD fee schedule increase factor of 2.8 percent for the CY 2024 OPPS (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.0 percent, less the proposed 0.2 percentage point productivity adjustment).

We propose that hospitals that fail to meet the Hospital OQR Program reporting requirements would be subject to an additional reduction of 2.0 percentage points from the OPD fee schedule increase factor adjustment to the conversion factor that would be used to calculate the OPPS payment rates for their services, as required by section 1833(t)(17) of the Act. For further discussion of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

To set the OPPS conversion factor for 2024, we propose to increase the CY 2023 conversion factor of $85.585 by 2.8 percent reflecting the proposed IPPS hospital market basket update. In accordance with section 1833(t)(9)(B) of the Act, we propose further to adjust the conversion factor for CY 2024 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to calculate an overall budget neutrality factor of 0.9974 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2024 IPPS wage indexes to those payments using the FY 2023 IPPS wage indexes, as adopted on a calendar year basis for the OPPS. We further propose to calculate an additional budget neutrality factor of 0.9975 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis.

For the CY 2024 OPPS, we propose to maintain the current rural adjustment policy, as discussed in section II.E of this proposed rule. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2024 budget neutrality adjustment factor for the cancer hospital payment adjustment by transitioning from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, we propose to apply a budget neutrality adjustment factor of 1.0005 to the conversion factor for the cancer hospital payment adjustment. In accordance with section 1833(t)(18)(C) of the Act, as added by section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255), requires that we reduce the target PCR by 0.01, which brings the proposed target PCR to 0.88. This is 0.01 less than the target PCR of 0.89 from CY 2021 through CY 2023, which was held at the pre-PHE target.

For this proposed rule, we estimated that proposed pass-through spending for drugs, biologicals, and devices for CY 2024 would equal approximately $234.1 million, which represents 0.26 percent of total projected CY 2024 OPPS spending. Therefore, the proposed conversion factor would be adjusted by the difference between the 0.16 percent estimate of pass-through spending for CY 2023 and the 0.26 percent estimate of proposed pass-through spending for CY 2024, resulting in a proposed decrease to the conversion factor for CY 2024 of 0.1 percent.

Proposed estimated payments for outliers would remain at 1.0 percent of total OPPS payments for CY 2024. We estimated for this proposed rule that outlier payments would be approximately 0.78 percent of total OPPS payments in CY 2023; the 1.00 percent for proposed outlier payments in CY 2024 would constitute a 0.22 percent increase in payment in CY 2024 relative to CY 2023.

For CY 2024, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the

requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above, but use a reduced OPD fee schedule update factor of 0.8 percent (that is, the proposed OPD fee schedule increase factor of 2.8 percent further reduced by 2.0 percentage points). This would result in a proposed reduced conversion factor for CY 2024 of $85.782 for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.706 in the conversion factor relative to hospitals that met the requirements).

In summary, for 2024, we propose to use a reduced conversion factor of $85.782 in the calculation of payments for hospitals that fail to meet the Hospital OQR Program requirements (a difference of −1.706 in the conversion factor relative to hospitals that met the requirements).

For 2024, we propose to use a conversion factor of $87.488 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of 2.8 percent for CY 2024, the required proposed wage index budget neutrality adjustment of approximately 0.9974, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9975, the proposed cancer hospital payment adjustment of 1.0005, and the proposed adjustment of an decrease of 0.1 percentage point of projected OPPS spending for the difference in pass-through spending, which results in a proposed conversion factor for CY 2024 of $87.488. The calculations we performed to determine the CY 2024 proposed conversion factor are shown in Table 3.

BILLING CODE 4120–01–P

Table 3. CALCULATION OF CY 2024 PROPOSED OPPS CONVERSION FACTOR

Start: CY 2023 Final OPPS Conversion Factor = **$85.585**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2023. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0016) and the percentage of outlier spending (0.01). as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2023. ➢ 1.0000– (0.0016+0.01) = 0.9884 *Step 1b:* Divide $85.585 by 0.9884 ➢ $85.585/0.9884 = **$86.589**
Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 0.9974. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $86.589. ➢ $86.589*0.9974 = **$86.364**
Step 3: Adjust the conversion factor by the proposed 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9975. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $86.364. ➢ $86.364*0.9975 = **$86.148**
Step 4: Adjust the conversion factor by the proposed cancer hospital payment adjustment of 1.0005. Because the PCR for cancer hospitals is declining between CY 2023 and CY 2024, it increases the amount of OPPS outpatient hospital spending for providers that are not cancer hospitals and is multiplied with $86.148. ➢ $86.148*1.0005 = **$86.191**
Step 5: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we are proposing to maintain our current policy, there is no impact on the conversion by this policy. ➢ $86.191*1.0000 = **$86.191**
Step 6a: Adjust the conversion factor by the proposed OPD fee schedule increase factor of 0.028 for CY 2024. The proposed OPD fee schedule increase factor increases outpatient hospital spending in CY 2024 over CY 2023 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2023.

➢ 1.0000+0.028 = 1.0280
Step 6b: Multiply $86.191 by 1.0280. ➢ $86.191*1.0280 = **$88.605**
Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2024. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0026) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2024. ➢ 1.0000– (0.0026+0.01) = 0.9874
Step 7b: Multiply $88.605 by 0.9874 to get the CY 2024 proposed OPPS conversion factor. ➢ $88.605/0.9874 = **$87.488**
Finish: **CY 2024 Proposed OPPS Conversion Factor = $87.488**

BILLING CODE 4120–01–C

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.B of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2024 OPPS. We refer readers to section II.H of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the internet on the CMS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2024 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under 42 CFR 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000 final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998 OPPS proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For 2024, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any

associated HOPD. We refer readers to the FY 2011 through FY 2023 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of ''frontier States'' as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 through 53370; for FY 2014, 78 FR 50590 through 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; and for FY 2023, 87 FR 49006.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2024 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and the permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in a prior FY. Beginning with FY 2024, we proposed to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 26973 through 26974). We also propose to continue the low wage index hospital policy, under which we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed discussion of all proposed changes to the FY 2024 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index for FY 2024 would not be less than 95 percent of its final wage index for FY 2023, and that for subsequent years, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We stated that we believe this policy would increase the predictability of IPPS payments for hospitals and mitigate instability and significant negative impacts to hospitals resulting from changes to the wage index. It would also eliminate the need for temporary and potentially uncertain transition adjustments to the wage index in the future due to specific policy changes or circumstances outside hospitals' control. Except for newly opened hospitals, we will apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it would not receive a cap for that first year because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted above).

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at: *https://www.census.gov/geo/reference/county-changes.html* (which, as of May 6, 2019, migrated to: *https://www.census.gov/programs-surveys/geography.html*). In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2024, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2024 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2024. Therefore, any policies and adjustments for the FY 2024 IPPS post-reclassified wage index would be reflected in the final CY 2024 OPPS wage index beginning on January 1, 2024. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) and the proposed FY 2024 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/acute-inpatient-pps/fy-2024-ipps-proposed-rule-home-page*. With regard to budget neutrality for the CY 2024 OPPS wage index, we refer readers to section II.B of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2024. We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26963 through 26986) for a detailed discussion of the proposed changes to the FY 2024 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)).

Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2024, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA). Furthermore, we propose that the wage index that would apply for CY 2024 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5-percent cap on wage index decreases.

For CMHCs, for CY 2024, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2024 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index to address wage index disparities. In addition, the wage index that would apply to CMHCs would include the 5-percent cap on wage index decreases. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2024 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2024 IPPS/LTCH PPS proposed rule (available for download via the website above) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2024. We are including the outmigration adjustment information from Table 2 associated with the FY 2024 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index*. At this link, readers will find a link to the proposed FY 2024 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB NO: 0938–0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. 100–04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the CY 2024 OPPS proposed rule Claims Accounting Narrative that is posted on our website. We propose to calculate the default ratios for CY 2024 using the most recent cost report data. We will update these ratios in the final rule with comment period if more recent cost report data are available.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS proposed rule and final rule with comment period. These CCRs with the upper limit will be available for download with each OPPS CY proposed rule and final rule on the CMS website. We refer readers to our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*; click on the link on the left of the page titled ''Hospital Outpatient Regulations and Notices'' and then select the relevant regulation to download the statewide CCRs and upper limit in the downloads section of the web page.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) Under Section 1833(t)(13)(B) of the Act for CY 2024

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding drugs, biologicals, brachytherapy sources, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before

calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2023.

For CY 2024, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2024

1. Background

Since the inception of the OPPS, which was authorized by the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106–113), the Congress added section 1833(t)(7), ''Transitional Adjustment to Limit Decline in Payment,'' to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as ''held harmless'' and their payments are often referred to as ''hold harmless'' payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPS and a ''pre-BBA amount.'' That is, cancer hospitals are permanently held harmless to their ''pre-BBA amount,'' and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The ''pre-BBA amount'' is the product of the hospital's reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The ''pre-BBA amount'' and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938–0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act (Pub. L. 111–148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 through 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the ''target PCR'') for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 4 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2023.

TABLE 4: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT PAYMENT-TO-COST RATIOS (PCRs), CY 2012 THROUGH CY 2023

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89

2. Proposed Policy for CY 2024

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114–255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the target PCR adjustment be reduced by 1.0 percentage point less than what would otherwise apply. Section 16002(b) also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or ''target PCR'') for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0 percentage point, to comply with section 16002(b) of the 21st Century Cures Act, and adjusted by the proposed post-Public Health Emergency transition as described later in this section. We are not proposing an additional reduction beyond the 1.0 percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2024.

To calculate the proposed CY 2024 target PCR, we would use the same extract of cost report data from HCRIS used to estimate costs for the CY 2024 OPPS which, in most cases, would be the most recently available hospital cost reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2022 claims data that we used to model the impact of the proposed CY 2024 APC relative payment weights (3,406 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2024 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2017 to 2022; however, the cost reporting periods were predominantly from fiscal years ending in 2021 and 2022. We then removed the cost report data of the 47 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also removed the cost report data of 14 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,345 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimate that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 86 percent of reasonable cost (weighted average PCR of .86). Therefore, after applying the 1.0 percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a target PCR equal to 0.85 for each cancer hospital.

However, we note that a proposed cancer hospital target PCR of 0.85 for CY 2024 is dramatically lower than the target PCR from previous years. Historically, as shown in Table 4, the target PCR for cancer hospitals has been between 0.88 and 0.92. In light of our concerns about the impact of the COVID–19 PHE on CY 2020 claims and cost data, we finalized a policy to continue the target PCR of 0.89 from CY 2021 for CY 2022 and for CY 2023 as an appropriate cancer hospital adjustment under our authority described in section 1833(t)(2)(E) of the Act. We believe the impact of the COVID–19 PHE claims and cost data used to calculate the target PCR of 0.85 may continue to have some limited influence on our target PCR calculations. However, we believe we should begin to take into consideration the PCR of non-cancer hospitals based on the most recently available data for calculating the target PCR. We do not

know if the changes in the data that have yielded a significantly lower PCR for non-cancer hospitals using the most recently available data are likely to continue in future years or if, when data from after the PHE is available, we will see the target PCR increase toward its historical norm. We are concerned that using the 0.85 target PCR calculated from the most recent data could lead to instability in cancer hospital adjustment payments and volatility in the PCR as we transition to utilizing post-PHE data. Therefore, in this CY 2024 OPPS/ASC proposed rule, we propose to transition from the target PCR of 0.89 we finalized for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reduce the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, utilizing this methodology for this CY 2024 OPPS/ASC proposed rule, we propose to reduce the CY 2023 target PCR of 0.89 by 1 percentage point and propose a cancer hospital target PCR of 0.88 for CY 2024.

Table 5 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2024, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2024 cancer hospital payment adjustment for each cancer hospital would be determined at cost report settlement and would depend on each hospital's CY 2024 payments and costs from the settled CY 2024 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

BILLING CODE 4120–01–P

TABLE 5: ESTIMATED CY 2024 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2024 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	43.9%
050660	USC Norris Cancer Hospital	30.2%
100079	Sylvester Comprehensive Cancer Center	41.9%
100271	H. Lee Moffitt Cancer Center & Research Institute	25.0%
220162	Dana-Farber Cancer Institute	41.1%
330154	Memorial Sloan-Kettering Cancer Center	56.9%
330354	Roswell Park Cancer Institute	19.1%
360242	James Cancer Hospital & Solove Research Institute	11.6%
390196	Fox Chase Cancer Center	22.1%
450076	M.D. Anderson Cancer Center	47.7%
500138	Seattle Cancer Care Alliance	39.4%

BILLING CODE 4120–01–C

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2023, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $8,625 (the fixed-dollar amount threshold) (87 FR 71788 through 71790). If the hospital's cost of furnishing a service exceeds both the multiplier threshold

and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2022 OPPS payments, using CY 2022 claims available for this CY 2024 OPPS proposed rule, is approximately 0.88 percent. Therefore, for CY 2022, we estimate that we did not meet the outlier target by 0.12 percent of total aggregated OPPS payments.

For this proposed rule, using CY 2022 claims data and CY 2023 payment rates, we estimate that the aggregate outlier payments for CY 2023 would be approximately 0.78 percent of the total CY 2023 OPPS payments. We provide estimated CY 2024 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital-Specific Impacts—Provider-Specific Data file on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.*

2. Outlier Calculation for CY 2024

For CY 2024, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for PHP outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. In this CY 2024 OPPS/ASC proposed rule, we propose to modify our outlier policy and which APCs are eligible for an outlier payment if a CMHC's cost for services exceeds 3.40 times the APC payment rate. The outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C of this proposed rule.

To ensure that the estimated CY 2024 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus $8,350.

We calculated the proposed fixed-dollar threshold of $8,350 using the standard methodology most recently used for CY 2023 (87 FR 71788 through 71790). For purposes of estimating outlier payments for CY 2024, we use the hospital-specific overall ancillary CCRs available in the April 2023 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2024 hospital outlier payments, we inflate the charges on the CY 2022 claims using the same proposed charge inflation factor of 1.118412 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27220). We used an inflation factor of 1.05755 to estimate CY 2023 charges from the CY 2022 charges reported on CY 2022 claims before applying CY 2023 CCRs to estimate the percent of outliers paid in CY 2023. The proposed methodology for determining these charge inflation factors is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27219 through 27220). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2024 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2024 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2024, we propose to apply an adjustment factor of 0.977799 to the CCRs that were in the April 2023 OPSF to trend them forward from CY 2023 to CY 2024. The methodology for calculating the proposed CCR adjustment factor, as well as the solicitation of comments on an alternative approach, is discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27221).

To model hospital outlier payments for the CY 2024 proposed rule, we apply the overall CCRs from the April 2023 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.977799 to approximate CY 2024 CCRs) to charges on CY 2022 claims that were adjusted (using the proposed charge inflation factor of 1.118412 to approximate CY 2024 charges). We simulated aggregated CY 2022 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2024 OPPS payments. We estimated that a proposed fixed-dollar threshold of $8,350, combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0 percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR

Program requirements, we proposed to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment From the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this CY 2024 OPPS/ASC proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B and the relative payment weight described in section II.A of this proposed rule. The national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available via the CMS website ''Hospital Outpatient Regulations and Notices'' and for most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available on the CMS website link above) is calculated by multiplying the proposed CY 2024 scaled weight for the APC by the CY 2024 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''Q4'', ''R'', ''S'', ''T'', ''U'', or ''V'' (as defined in Addendum D1 to this proposed rule, which is available via the internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of ''Q1'' and ''Q2'') qualify for separate payment. We note that, although blood and blood products with status indicator ''R'' and brachytherapy sources with status indicator ''U'' are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the ''full'' national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the ''reduced'' national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9805 times the ''full'' national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2024 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS/ASC final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

$X = .60 * (\text{national unadjusted payment rate})$.

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2024 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) ''Lugar'' hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. We propose to continue to apply for the CY 2024 OPPS wage index any adjustments for the FY 2024 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment, a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010, and an adjustment to the wage index for certain low wage index hospitals. For further discussion of the wage index we propose to apply for the CY 2024 OPPS, we refer readers to section II.C of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173). Addendum L to this proposed rule (which is available via the internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2024 IPPS wage index, which are listed in Table 3 associated with the FY 2024 IPPS proposed rule and available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* (Click on the link on the left side of the screen titled ''FY 2024 IPPS Proposed Rule Home

Page'' and select ''FY 2024 Proposed Rule Tables.'') This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = .40 * (national unadjusted payment rate).

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2024 full national unadjusted payment rate for APC 5071 is $675.15. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $661.98. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the proposed full national unadjusted payment is approximately $405.09 (.60 * $675.15). The labor-related portion of the proposed reduced national adjusted payment is approximately $397.19 (.60 * $675.15).

Step 2 & 3. The FY 2024 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2024 wage index policies, is 1.3631.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately $522.18 ($405.09 *1.3631). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately $541.41 ($397.19 * 1.3631).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately $270.06 (.40 * $675.15). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately $264.79 (.40 * $661.98).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately $822.24 ($552.18 + $270.06). The sum of the portions of the proposed reduced national adjusted payment is approximately $806.20 ($541.41 + $264.79).

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
$882.24	$806.20

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than 20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B

coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116–260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amends section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B, ''Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests,'' of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through 2026 (and the corresponding reduction in coinsurance) is 85 percent (with beneficiary coinsurance equal to 15 percent).

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA are currently being implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. As such, we issued final guidance for the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act on February 9, 2023.[4] [5] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare*. We also refer readers to the CY 2024 Medicare Physician Fee Schedule (PFS) proposed rule for a detailed discussion of proposals related to inflation-adjusted beneficiary coinsurance and Medicare payment for Medicare Part B rebatable drugs.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) requires under the ASC payment system that in the case of a Part B rebatable drug, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in calendar quarters in which the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the amount specified in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) o the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the inflation-adjusted payment amount of a Part B rebatable drug exceeds the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act), the Part B payment will, subject to the deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount.

In this proposed rule, we propose to codify the OPPS program payment and cost sharing amounts for Part B rebatable drugs as required by section 1833(t)(8)(F) by adding a new paragraph (e) to § 419.41, which cross-references the regulations proposed in the CY 2024 PFS proposed rule (§§ 410.152(m) and 489.30(b)(6)). We also propose to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41. Similarly, we propose to codify the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising § 416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), as proposed in the CY 2024 PFS proposed rule to codify the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation. We are not proposing any changes to the ASC regulations at 42 CFR part 416 to reflect the Medicare payment amount for Part B rebatable drugs with prices increasing at a rate faster than inflation, because 42 CFR

[4] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf.*

[5] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies ''inflation-adjusted coinsurance'' in the ''Notes'' column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

416.171(b) already incorporates, for the ASC payment system, the payment amounts that apply for the OPPS under 42 CFR part 419. Part 419 would include our proposed new § 419.41(e), which addresses Medicare payment for Part B rebatable drugs under the OPPS.

2. Proposed OPPS Copayment Policy

For CY 2024, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. (We refer readers to the November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458).) In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. (We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles.) The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2024 are included in Addenda A and B to this proposed rule (which are available via the internet on the CMS website).

As discussed in section XIV.E of this proposed rule, for CY 2024, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.
- If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).
- If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.
- If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).
- If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20-percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, $135.03 is approximately 20 percent of the full national unadjusted payment rate of $675.15. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule with comment period (which are available via the internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H of this proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H of this proposed rule, with and without the

rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2024 are shown in Addenda A and B to this proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the proposed CY 2024 OPD increase factor discussed in section II.B of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on HOPD claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical Association (AMA), and consists of Category I, II, III, MAAA, and PLAA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI ''Proposed CY 2024 Payment Status and Comment Indicators'' of this proposed rule, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a complete list of the proposed status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, 67 new HCPCS codes were established and made effective on April 1, 2023. Through the April 2023 OPPS quarterly update CR (Transmittal 11937, Change Request 13136, dated March 31, 2023), we recognized several new HCPCS codes for payment under the OPPS. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 6 (New HCPCS Codes Effective April 1, 2023). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The new codes effective April 1, 2023, are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed status indicators and definitions used under the OPPS can be found in Addendum D1 to this proposed rule, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 6: NEW HCPCS CODES EFFECTIVE APRIL 1, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor
A2019	Kerecis omega3 marigen shield, per square centimeter
A2020	Ac5 advanced wound system (ac5)
A2021	Neomatrix, per square centimeter
A4341	Indwelling intraurethral drainage device with valve, patient inserted, replacement only, each
A4342	Accessories for patient inserted indwelling intraurethral drainage device with valve, replacement only, each
A4560	Neuromuscular electrical stimulator (nmes), disposable, replacement only
A6590	External urinary catheters; disposable, with wicking material, for use with suction pump, per month
A6591	External urinary catheter; non-disposable, for use with suction pump, per month
A7049	Expiratory positive airway pressure intranasal resistance valve
C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	Injection, tremelimumab-actl, 1 mg
C9148	Injection, teclistamab-cqyv, 0.5 mg
C9149	Injection, teplizumab-mzwv, 5 mcg
E0677	Non-pneumatic sequential compression garment, trunk
E0711	Upper extremity medical tubing/lines enclosure or covering device, restricts elbow range of motion
E1905	Virtual reality cognitive behavioral therapy device (cbt), including pre-programmed therapy software
J0208	Injection, sodium thiosulfate, 100 mg
J0218	Injection, olipudase alfa-rpcp, 1 mg
J0612	Injection, calcium gluconate (fresenius kabi), per 10 mg
J0613	Injection, calcium gluconate (wg critical care), per 10 mg
J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9196	Injection, gemcitabine hydrochloride (accord), not therapeutically equivalent to j9201, 200 mg
J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg

CY 2023 HCPCS Code	CY 2023 Long Descriptor
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
K1006	Suction pump, home model, portable or stationary, electric, any type, for use with external urine management system
K1035	Molecular diagnostic test reader, nonprescription self-administered and self-collected use, fda approved, authorized or cleared
L8678	Electrical stimulator supplies (external) for use with implantable neurostimulator, per month
M0010	Enhancing oncology model (eom) monthly enhanced oncology services (meos) payment for eom enhanced services
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg
0364U	Oncology (hematolymphoid neoplasm), genomic sequence analysis using multiplex (PCR) and next-generation sequencing with algorithm, quantification of dominant clonal sequence(s), reported as presence or absence of minimal residual disease (MRD) with quantitation of disease burden, when appropriate
0365U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of bladder cancer
0366U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, algorithm reported as a probability of recurrent bladder cancer
0367U	Oncology (bladder), analysis of 10 protein biomarkers (A1AT, ANG, APOE, CA9, IL8, MMP9, MMP10, PAI1, SDC1 and VEGFA) by immunoassays, urine, diagnostic algorithm reported as a risk score for probability of rapid recurrence of recurrent or persistent cancer following transurethral resection

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0368U	Oncology (colorectal cancer), evaluation for mutations of APC, BRAF, CTNNB1, KRAS, NRAS, PIK3CA, SMAD4, and TP53, and methylation markers (MYO1G, KCNQ5, C9ORF50, FLI1, CLIP4, ZNF132 and TWIST1), multiplex quantitative polymerase chain reaction (qPCR), circulating cell-free DNA (cfDNA), plasma, report of risk score for advanced adenoma or colorectal cancer
0369U	Infectious agent detection by nucleic acid (DNA and RNA), gastrointestinal pathogens, 31 bacterial, viral, and parasitic organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique
0370U	Infectious agent detection by nucleic acid (DNA and RNA), surgical wound pathogens, 34 microorganisms and identification of 21 associated antibioticresistance genes, multiplex amplified probe technique, wound swab
0371U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogen, semiquantitative identification, DNA from 16 bacterial organisms and 1 fungal organism, multiplex amplified probe technique via quantitative polymerase chain reaction (qPCR), urine
0372U	Infectious disease (genitourinary pathogens), antibiotic-resistance gene detection, multiplex amplified probe technique, urine, reported as an antimicrobial stewardship risk score
0373U	Infectious agent detection by nucleic acid (DNA and RNA), respiratory tract infection, 17 bacteria, 8 fungus, 13 virus, and 16 antibiotic-resistance genes, multiplex amplified probe technique, upper or lower respiratory specimen
0374U	Infectious agent detection by nucleic acid (DNA or RNA), genitourinary pathogens, identification of 21 bacterial and fungal organisms and identification of 21 associated antibiotic-resistance genes, multiplex amplified probe technique, urine
0375U	Oncology (ovarian), biochemical assays of 7 proteins (follicle stimulating hormone, human epididymis protein 4, apolipoprotein A-1, transferrin, beta-2 macroglobulin, prealbumin [ie, transthyretin], and cancer antigen 125), algorithm reported as ovarian cancer risk score
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancerspecific mortality, includes predictive algorithm to androgen deprivationtherapy response, if appropriate
0377U	Cardiovascular disease, quantification of advanced serum or plasma lipoprotein profile, by nuclear magnetic resonance (NMR) spectrometry with report of a lipoprotein profile (including 23 variables)
0378U	RFC1 (replication factor C subunit 1), repeat expansion variant analysis by traditional and repeat-primed PCR, blood, saliva, or buccal swab

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0379U	Targeted genomic sequence analysis panel, solid organ neoplasm, DNA (523 genes) and RNA (55 genes) by nextgeneration sequencing, interrogation for sequence variants, gene copy number amplifications, gene rearrangements, microsatellite instability, and tumor mutational burden
0380U	Drug metabolism (adverse drug reactions and drug response), targeted sequence analysis, 20 gene variants and CYP2D6 deletion or duplication analysis with reported genotype and phenotype
0381U	Maple syrup urine disease monitoring by patient-collected blood card sample, quantitative measurement of alloisoleucine, leucine, isoleucine, and valine, liquid chromatography with tandem mass spectrometry (LCMS/MS)
0382U	Hyperphenylalaninemia monitoring by patient-collected blood card sample, quantitative measurement of phenylalanine and tyrosine, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
0383U	Tyrosinemia type I monitoring by patient-collected blood card sample, quantitative measurement of tyrosine, phenylalanine, methionine, succinylacetone, nitisinone, liquid chromatography with tandem mass spectrometry (LC-MS/MS)
0384U	Nephrology (chronic kidney disease), carboxymethyllysine, methylglyoxal hydroimidazolone, and carboxyethyl lysine by liquid chromatography with tandem mass spectrometry (LCMS/MS) and HbA1c and estimated glomerular filtration rate (GFR), with risk score reported for predictive progression to high-stage kidney disease
0385U	Nephrology (chronic kidney disease), apolipoprotein A4 (ApoA4), CD5 antigen-like (CD5L), and insulin-like growth factor binding protein 3 (IGFBP3) by enzyme-linked immunoassay (ELISA), plasma, algorithm combining results with HDL, estimated glomerular filtration rate (GFR) and clinical data reported as a risk score for developing diabetic kidney disease
0386U	Gastroenterology (Barrett's esophagus), P16, RUNX3, HPP1, and FBN1 methylation analysis, prognostic and predictive algorithm reported as a risk score for progression to high-grade dysplasia or esophageal cancer

2. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2023 update, 97 new codes were established and made effective July 1, 2023. Through the July 2023 OPPS quarterly update CR (Transmittal 12077, Change Request 13210, dated June 13, 2023), we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 7 (New HCPCS Codes Effective July 1, 2023). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator ''NP'' in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

TABLE 7: NEW HCPCS CODES EFFECTIVE JULY 1, 2023

CY 2023 HCPCS Code	CY 2023 Long Descriptor
C9150	Xenon Xe-129 hyperpolarized gas, diagnostic, per study dose
C9151	Injection, pegcetacoplan, 1 mg
C9784	Gastric restrictive procedure, endoscopic sleeve gastroplasty, with esophagogastroduodenoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components.
C9786	Echocardiography image post processing for computer aided detection of heart failure with preserved ejection fraction, including interpretation and report
C9787	Gastric electrophysiology mapping with simultaneous patient symptom profiling
J0137	Injection, acetaminophen (hikma) not therapeutically equivalent to J0131, 10 mg
J0206	Injection, allopurinol sodium, 1 mg
J0216	Injection, alfentanil hydrochloride, 500 micrograms
J0457	Injection, aztreonam, 100 mg
J0665	Injection, bupivicaine, not otherwise specified, 0.5 mg
J0736	Injection, clindamycin phosphate, 300 mg
J0737	Injection, clindamycin phosphate (baxter), not therapeutically equivalent to J0736, 300 mg
J1440	Fecal microbiota, live - jslm, 1 ml
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1805	Injection, esmolol hydrochloride, 10 mg
J1806	Injection, esmolol hydrochloride (wg critical care) not therapeutically equivalent to J1805, 10 mg
J1811	Insulin (fiasp) for administration through dme (i.e., insulin pump) per 50 units
J1812	Insulin (fiasp), per 5 units
J1813	Insulin (lyumjev) for administration through dme (i.e., insulin pump) per 50 units
J1814	Insulin (lyumjev), per 5 units
J1836	Injection, metronidazole, 10 mg
J1920	Injection, labetalol hydrochloride, 5 mg
J1921	Injection, labetalol hydrochloride (hikma) not therapeutically equivalent to J1820, 5 mg
J1941	Injection, furosemide (furoscix), 20 mg
J1961	Injection, lenacapavir, 1 mg
J2249	Injection, remimazolam, 1 mg
J2305	Injection, nitroglycerin, 5 mg
J2329	Injection, ublituximab-xiiy, 1mg
J2371	Injection, phenylephrine hydrochloride, 20 micrograms
J2372	Injection, phenylephrine hydrochloride (biorphen), 20 micrograms

CY 2023 HCPCS Code	CY 2023 Long Descriptor
J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J2561	Injection, phenobarbital sodium (sezaby), 1 mg
J2598	Injection, vasopressin, 1 unit
J2599	Injection, vasopressin (american regent) not therapeutically equivalent to J2598, 1 unit
J2806	Injection, sincalide (maia) not therapeutically equivalent to j2805, 5 micrograms
J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9029	Injection, nadofaragene firadenovec-vncg, per therapeutic dose
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	Injection, tremelimumab-actl, 1 mg
J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	Injection, teplizumab-mzwv, 5 mcg
Q4272	ESA no a, per square centimeter
Q4273	Eason air, per square centimeter
Q4274	ESA no ac, per square centimeter
Q4275	Eason aca, per square centimeter
Q4276	Orion, per square centimeter
Q4277	Woundplus membrane or e-graft, per square centimeter
Q4278	Epieffect, per square centimeter
Q4280	Xcell amnio matrix, per square centimeter
Q4281	Barrera sl or barrera dl, per square centimeter
Q4282	Cygnus dual, per square centimeter
Q4283	Biovance tri-layer or biovance 3l, per square centimeter
Q4284	Dermabind sl, per square centimeter
Q5131	Injection, adalimumab-aacf (idacio), biosimilar, 20 mg
0791T	Motor-cognitive, semi-immersive virtual reality–facilitated gait training, each 15 minutes (List separately in addition to code for primary procedure)
0792T	Application of silver diamine fluoride 38%, by a physician or other qualified health care professional

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0794T	Patient-specific, assistive, rules-based algorithm for ranking pharmaco-oncologic treatment options based on the patient's tumor-specific cancer marker information obtained from prior molecular pathology, immunohistochemical, or other pathology results which have been previously interpreted and reported separately
0795T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0796T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component (when an existing right ventricular single leadless pacemaker exists to create a dual-chamber leadless pacemaker system)
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0798T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; complete system (ie, right atrial and right ventricular pacemaker components)
0799T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right atrial pacemaker component
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0801T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; dual-chamber system (ie, right atrial and right ventricular pacemaker components)
0802T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right atrial pacemaker component
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0804T	Programming device evaluation (in person) with iterative adjustment of implantable device to test the function of device and to select optimal permanent programmed values, with analysis, review, and report, by a physician or other qualified health care professional, leadless pacemaker system in dual cardiac chambers
0805T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); percutaneous femoral vein approach
0806T	Transcatheter superior and inferior vena cava prosthetic valve implantation (ie, caval valve implantation [CAVI]); open femoral vein approach
0807T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with previously acquired computed tomography (CT) images, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0808T	Pulmonary tissue ventilation analysis using software-based processing of data from separately captured cinefluorograph images; in combination with computed tomography (CT) images taken for the purpose of pulmonary tissue ventilation analysis, including data preparation and transmission, quantification of pulmonary tissue ventilation, data review, interpretation and report
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0387U	Oncology (melanoma), autophagy and beclin 1 regulator 1 (AMBRA1) and loricrin (AMLo) by immunohistochemistry, formalinfixed paraffin-embedded (FFPE) tissue, report for risk of progression
0388U	Oncology (non-small cell lung cancer), next-generation sequencing with identification of single nucleotide variants, copy number variants, insertions and deletions, and structural variants in 37 cancer-related genes, plasma, with report for alteration detection
0389U	Pediatric febrile illness (Kawasaki disease [KD]), interferon alphainducible protein 27 (IFI27) and mast cell-expressed membrane protein 1 (MCEMP1), RNA, using reverse transcription polymerase chain reaction (RT-qPCR), blood, reported as a risk score for KD
0390U	Obstetrics (preeclampsia), kinase insert domain receptor (KDR), Endoglin (ENG), and retinol-binding protein 4 (RBP4), by immunoassay, serum, algorithm reported as a risk score
0391U	Oncology (solid tumor), DNA and RNA by next-generation sequencing, utilizing formalin-fixed paraffin-embedded (FFPE) tissue, 437 genes, interpretive report for single nucleotide variants, splicesite variants, insertions/deletions, copy number alterations, gene fusions, tumor mutational burden, and microsatellite instability, with algorithm quantifying immunotherapy response score
0392U	Drug metabolism (depression, anxiety, attention deficit hyperactivity disorder [ADHD]), gene-drug interactions, variant analysis of 16 genes, including deletion/duplication analysis of CYP2D6, reported as impact of gene-drug interaction for each drug
0393U	Neurology (eg, Parkinson disease, dementia with Lewy bodies), cerebrospinal fluid (CSF), detection of misfolded α-synuclein protein by seed amplification assay, qualitative
0394U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), 16 PFAS compounds by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0395U	Oncology (lung), multi-omics (microbial DNA by shotgun nextgeneration sequencing and carcinoembryonic antigen and osteopontin by immunoassay), plasma, algorithm reported as malignancy risk for lung nodules in early-stage disease
0396U	Obstetrics (pre-implantation genetic testing), evaluation of 300000 DNA single-nucleotide polymorphisms (SNPs) by microarray, embryonic tissue, algorithm reported as a probability for single-gene germline conditions
0397U	Oncology (non-small cell lung cancer), cell-free DNA from plasma, targeted sequence analysis of at least 109 genes, including sequence variants, substitutions, insertions, deletions, select rearrangements, and copy number variations
0398U	Gastroenterology (Barrett esophagus), P16, RUNX3, HPP1, and FBN1 DNA methylation analysis using PCR, formalin-fixed paraffin-embedded (FFPE) tissue, algorithm reported as risk score for progression to high-grade dysplasia or cancer

CY 2023 HCPCS Code	CY 2023 Long Descriptor
0399U	Neurology (cerebral folate deficiency), serum, detection of anti-human folate receptor IgGbinding antibody and blocking autoantibodies by enzyme-linked immunoassay (ELISA), qualitative, and blocking autoantibodies, using a functional blocking assay for IgG or IgM, quantitative, reported as positive or not detected
0400U	Obstetrics (expanded carrier screening), 145 genes by nextgeneration sequencing, fragment analysis and multiplex ligationdependent probe amplification, DNA, reported as carrier positive or negative
0401U	Cardiology (coronary heart disease [CAD]), 9 genes (12 variants), targeted variant genotyping, blood, saliva, or buccal swab, algorithm reported as a genetic risk score for a coronary event

BILLING CODE 4120–01–C

3. October 2023 HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2023, in the CY 2024 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2023 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2024, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to those new HCPCS codes that will be effective October 1, 2023, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2024 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

4. January 2024 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2024, in the CY 2024 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2025 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2024, we propose to include the new Level II HCPCS codes effective January 1, 2024, in Addendum B to the CY 2024 OPPS/ASC final rule with comment period, which would be incorporated in the January 2024 OPPS quarterly update CR. Specifically, for CY 2024, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2024, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2024 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's final rule.

For the CY 2024 OPPS update, we received the CPT codes that will be effective January 1, 2024, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator. Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2024 CPT codes in Addendum O, specifically under the column labeled ''CY 2024 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.'' The final HCPCS code numbers will be included in the CY 2024 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2024 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2024. Because the CPT codes listed in Addendum B appear with short descriptors only, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2024 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 8 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes) below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 8: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period

B. Proposed OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3 of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2024, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

2. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2024 OPPS update will be discussed in the relevant specific sections throughout the CY 2024 OPPS/ASC final rule with comment period.

In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ''2 times rule''). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2024, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2024 OPPS update, we identified the APCs with violations of the 2 times rule and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we propose a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we are not proposing a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2024 included in this proposed rule are related to changes in costs of services that were observed in the CY 2022 claims data available for CY 2024 ratesetting. Addendum B to this proposed rule identifies with a comment indicator ''CH'' those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2023, OPPS Addendum B Update, which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Addendum-A-and-Addendum-B-Updates*.

3. Proposed APC Exceptions to the 2 Times Rule

Taking into account the APC changes that we propose to make for CY 2024, we reviewed all of the APCs for which we identified 2 times rule violations to

determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2022 claims data available for this proposed rule, we found 21 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2024 and found that all of the 21 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2022 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 9 below. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 9 of this proposed rule lists the 21 APCs for which we propose to make an exception under the 2 times rule for CY 2024 based on the criteria cited above and claims data submitted between January 1, 2022 and December 31, 2022, and processed on or before December 31, 2022, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

TABLE 9: PROPOSED CY 2024 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5071	Level 1 Excision/ Biopsy/ Incision and Drainage
5301	Level 1 Upper GI Procedures
5303	Level 3 Upper GI Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5612	Level 2 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5721	Level 1 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5741	Level 1 Electronic Analysis of Devices
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. Proposed New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from

a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for a pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment* on the CMS website and then follow the instructions to access the MEARISTM system for OPPS New Technology APC applications.

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ''T'' (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2023, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0–$10)) to the highest cost band assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for New Technology APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers' payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have very low annual volume, which we consider to be fewer than 100 claims (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access to new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy, in the CY 2019 OPPS/ASC final rule with comment period, to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPS/ASC final rule (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2024, we included the

proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

2. Procedures Assigned to New Technology APC Groups for CY 2024

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2024, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology—Level 24 ($3001–$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology—Level 24 ($3001-$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[6] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA package insert describes one of the steps for administering Luxturna as, ''after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana.''

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[7] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself.

CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC proposed rule (85 FR 48832), we proposed to establish a new HCPCS code, C97X1 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. We stated that we believed this new HCPCS code accurately described the unique service associated with intraocular administration of HCPCS code J3398. We recognized that CPT code 67036 represents a clinically similar procedure and process that approximates similar resource utilization to C97X1. However, we also recognized that it is not prudent for the code that describes the administration of this unique gene therapy, C97X1, to be assigned to the same C–APC to which CPT code 67036 is assigned, as this would package the primary therapy, HCPCS code J3398, into the code that represents the process to administer the gene therapy.

Therefore, for CY 2021, we proposed to assign the services described by C97X1 to a New Technology APC with a cost band that contains the geometric mean cost for CPT code 67036. The placeholder code C97X1 was replaced by HCPCS code C9770. For CY 2021, we finalized our proposal to create HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent), and we assigned this code to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS code C9770 to APC 1561 (New Technology—Level 24 ($3001–$3500)) using the geometric mean cost of CPT code 67036.

CY 2023 was the first year that claims data were available for HCPCS code C9770; so we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023.

CPT code 0810T 9*Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies*) will be effective July 1, 2023. We recognize the similarity between HCPCS

[6] Luxturna. FDA Package Insert. Available: *https://www.fda.gov/media/109906/download*.

[7] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/pdf/Reimbursement_Guide_for_Treatment_Centers_Interactive_010418_FINAL.pdf*.

code C9770 and CPT code 0810T; therefore, we propose to delete HCPCS code C9770 effective December 31, 2023, and to recognize CPT code 0810T starting January 1, 2024. We propose to determine the payment rate for the procedure using the claims data for HCPCS code C9770. Similar to CY 2023, for CY 2024, given that there are only 10 single frequency claims available for ratesetting, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy and to use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims from the 4-year lookback period, we determined the geometric mean cost to be $3,944, the arithmetic mean cost to be $4,192, and the median cost to be $4,148. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,192 falls within the cost band for New Technology APC 1563 (New Technology—Level 26 ($4001–$4500)). Therefore, we propose to assign CPT code 0810T to APC 1563 for CY 2024. Additionally, we propose to perform a similar analysis using updated claims data in the CY 2024 OPPS/ASC final rule with comment period and update the APC placement as needed.

Please refer to Table 10 below for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9770 and CPT code 0810T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 10: CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9770 AND CPT CODE 0810T

HCPCS Code	Long Descriptor	CY 2023 OPPS SI	CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9770	Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent	T	1562	D	N/A
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	E1	N/A	T	1563

b. Bronchoscopy With Transbronchial Ablation of Lesion(s) by Microwave Energy (APC 1562)

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3–D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (for example, aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500.

In claims data available for CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the universal low volume APC policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to determine an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. We found the geometric mean cost for the service to be approximately $2,693, the arithmetic mean cost to be approximately $3,086, and the median cost to be approximately $3,708. The median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we assigned HCPCS code C9751 to APC 1562 for CY 2021.

In CY 2022, we again used the claims data from CY 2019 for HCPCS code C9751. Because the claims data was unchanged from when it was used in CY 2021, the values for the geometric mean cost ($2,693), the arithmetic mean cost ($3,086), and the median cost ($3,708) for the service described by HCPCS code C9751 remained the same. The highest cost metric using these methodologies was again the median and within the

cost band for New Technology APC 1562 (New Technology—Level 25 ($3,501–$4,000)). Therefore, we continued to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3,501–$4,000)), with a payment rate of $3,750.50 for CY 2022.

There were no claims reported in CY 2020, CY 2021, or CY 2022 for HCPCS code C9751. Therefore, for CY 2024, the only available claims for HCPCS code C9751 continue to be from CY 2019; and the reported claims are the same claims used to calculate the payment rate for the service in the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period. Given the low number of claims for this procedure, we propose to continue to designate this procedure as a low volume procedure under our universal low volume policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the procedure to the appropriate New Technology APC. Because our proposal uses the same claims as we used for CY 2021, CY 2022, and CY 2023, the same values for the geometric mean cost, arithmetic mean cost, and the median cost are used to propose a payment rate for CY 2024. Once again, the median ($3,708) was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology continues to fall within the cost band for New Technology APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we propose to continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a proposed payment rate of $3,750.50 for CY 2024.

Please refer to Table 11 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9751 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 11: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]	T	1562

c. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1518, 1521, and 1522)

Effective January 1, 2020, we assigned three CPT codes (78431, 78432, and 78433) that describe the services associated with cardiac PET/CT studies to New Technology APCs. CPT code 78431 was assigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. CPT codes 78432 and 78433 were assigned to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50. We did not receive any claims data for these services for either of the CY 2021 or CY 2022 OPPS proposed or final rules. Therefore, we continued to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50 in CY 2021 and CY 2022. Likewise, we continued to assign CPT codes 78432 and 78433 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50.

For CY 2023, we used CY 2021 claims data to determine the payment rates for CPT codes 78431, 78432, and 78433. Based on our analysis of the available claims data, for CY 2023, we assigned CPT code 78431 to APC 1523 (New Technology—Level 23 ($2501–$3000)) with a payment rate of $2,750.50; CPT code 78432 to APC 1520 (New Technology—Level 20 ($1801–$1900)) with a payment rate of $1,850.50 based on the application of the universal low-volume policy; and CPT code 78433 to APC 1521 (New Technology—Level 21 ($1901–$2000)) with a payment rate of $1,950.50.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. CPT code 78431 had over 22,000 single frequency claims in CY 2022. The geometric mean for CPT code 78431 was approximately $2,300, which is an amount that is below the cost band for APC 1523 (New Technology—Level 23 ($2501–$3000)), where the procedure is currently assigned. We propose, for CY 2024, that CPT code 78431 be reassigned to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50. Please refer to Table 12 below for the proposed New Technology APC and status indicator assignments for CPT code 78431.

There were only six single frequency claims in CY 2022 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Using available claims data from CY 2021 and CY 2022, our analysis found the geometric mean cost of the service is approximately $1,658, the arithmetic mean cost of the service is approximately $1,445, and the median cost of the service is approximately $1,562. The geometric mean was the statistical methodology that estimated the highest cost for the service. The geometric mean cost of $1,658, is an amount that is below the

cost band for APC 1520 (New Technology—Level 20 ($1801–$1900)), where the procedure is currently assigned. Therefore, we propose, for CY 2024, to assign CPT code 78432 to APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50. Please refer to Table 12 for the proposed New Technology APC and status indicator assignments for CPT code 78432.

There were over 1200 single frequency claims for CPT code 78433 in CY 2022. The geometric mean for CPT code 78433 was approximately $1,960, which is an amount that is within the cost band for APC 1521 (New Technology—Level 21 ($1901–$2000)), to which it is currently assigned. Therefore, for CY 2024, we propose to continue to assign CPT code 78433 to APC 1521 with a payment rate of $1,950.50.

Please refer to Table 12 below for the proposed OPPS New Technology APC and status indicator assignment for CPT codes 78431, 78432, and 78433 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 12: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed OPPS CY 2024 APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1523	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1520	S	1518
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1521	S	1521

BILLING CODE 4120–01–C

d. V–Wave Medical Interatrial Shunt Procedure (APC 1590)

A randomized, double-blinded, controlled IDE study is currently in progress for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-

Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to New Technology APC 1589 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to New Technology APC 1590 (New Technology—Level 39 ($15,001–$20,000)), which reflects the cost of receiving the interatrial shunt one-half of the time the procedure is performed.

For CY 2022, we used the same claims data from CY 2019 that we did for the CY 2021 OPPS final rule with comment period. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2022. For CY 2023 we used claims data from CY 2019 through CY 2022. Because there were no claims reporting HCPCS code C9758, we continued to assign HCPCS code C9758 to New Technology APC 1590 with a payment rate of $17,500.50 for CY 2023.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9758 was effective January 1, 2020, we have no claims data at this time. Because we have no claims data, for CY 2024, we propose to continue to assign HCPCS code C9758 to New Technology APC 1590 with a proposed payment rate of $17,500.50.

Please refer to Table 13 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9758 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 13: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, transesophageal C9758 echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	T	1590

e. Corvia Medical Interatrial Shunt Procedure (APC 1592)

On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate payment for the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. But unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to New Technology APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ''or placebo control,'' from the descriptor. In CY 2022, we used the same claims data as was used in the CY 2021 OPPS final rule to determine the payment rate for HCPCS code C9760 because there were no claims for this service in CY 2019, the

year used for ratesetting for CY 2022. Accordingly, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2022. For CY 2023, we used claims data from CY 2021 through CY 2022 to determine the payment rate for HCPCS code C9760. Because there were no claims for this service, we continued to assign HCPCS code C9760 to New Technology APC 1592 in CY 2023.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There was only one claim for HCPCS code C9760 within this time period. As this is below the threshold of 100 claims for a service within a year, we would designate C9760 as a low volume service and apply our universal low volume APC policy. Under this policy, we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code C9760 to the appropriate New Technology APC. Using the only one claim available for HCPCS code C9760, the geometric mean, arithmetic mean, and median costs are estimated to be approximately $7945 for this service. However, because there is only a single claim for HCPCS code C9760, its payment rate appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Therefore, we propose to continue assigning HCPCS code C9760 to New Technology APC 1592.

Please refer to Table 14 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9760 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 14: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-RANDOMIZED, NON-BLINDED INTERATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy	T	1592

f. Supervised Visits for Esketamine Self-Administration (APCs 1513 and 1518)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant, for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. Patients must be monitored by a health care provider for at least 2 hours after receiving their esketamine nasal spray dose, the prescriber and patient must both sign a Patient Enrollment Form, and the product must only be administered in a certified medical office where the health care provider can monitor the patient.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of post-administration observation of the patient under direct supervision of a health care professional. Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. This is the first FDA approval of esketamine for any use. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients require either two devices (for a 56 mg dose) or three devices (for an 84 mg dose) per treatment.

Please refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. For CY 2020, HCPCS code G2082 was assigned to New Technology APC 1508 (New Technology—Level 8 ($601–$700)) with a payment rate of $650.50. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine. For CY 2020, HCPCS code G2083 was assigned to New Technology APC 1511 (New Technology—Level 11 ($901–$1000)) with a payment rate of $950.50. Please see the CY 2021 OPPS/

ASC final rule with comment period (85 FR 85948), CY 2022 OPPS/ASC final rule with comment period (86 FR 63538), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71816–71817) for the updates to the APC assignments for G2082 and G2083 we have made in past rules.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2024, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to New Technology APC 1513 (New Technology—Level 13 ($1101–$1200)) with a payment rate of $1,150.50 based on its geometric mean cost of $1,138, which was calculated using the available 294 single frequency claims from CY 2022 claims data. We also propose to assign HCPCS code G2083 to New Technology APC 1518 (New Technology—Level 18 ($1601–$1700)) with a payment rate of $1,650.50 based on its geometric mean cost of $1,693, which was calculated using the available 1581 single frequency claims from CY 2022 claims data. We note, as we have begun to gather adequate claims data on these codes, we are considering placing HCPCS codes G2082 and G2083 in clinical APCs through future rulemaking.

The proposed New Technology APC and status indicator assignments for HCPCS codes G2082 and G2083 are shown in Table 15. The proposed CY 2024 payment rates for these HCPCS codes can be found in Addendum B to this proposed rule.

TABLE 15: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1512	S	1513
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1516	S	1518

g. DARI Motion Procedure (APC 1505)

Effective January 1, 2022, CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) is associated with the DARI Motion Procedure, a service that provides human motion analysis to aid clinicians in pre- and post-operative surgical intervention and in making other treatment decisions, including selecting the best course of physical therapy and rehabilitation. The technology consists of eight cameras that surround a patient, which send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin. For CY 2022, we assigned CPT code 0693T to New Technology APC 1505 (New Technology—Level 5 ($301–$400)). For CY 2023, the OPPS payment rates were based on claims submitted between January 1, 2021, and December 31, 2021, processed through June 30, 2022. Due to its effective date of January 1, 2022, there were no claims available for CPT code 0693T for rate setting in CY 2023. Therefore, in CY 2023, we continued to assign CPT code 0693T to New Technology APC 1505.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although CPT code 0693T was effective January 1,

2022, we have no claims data at this time. Because we have no claims data, for CY 2024, we propose to continue to assign CPT code 0693T to APC 1505 with a proposed payment rate of $350.50.

Please refer to Table 16 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0693T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 16: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

h. Liver Histotripsy Service (APC 1575)

CPT code 0686T (Histotripsy (*i.e.,* non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors located in the liver.[8] When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed each time it is reported on a claim. For CY 2023, we assigned CPT code 0686T to New Technology APC 1575 (New Technology—Level 38 ($10,000–$15,000) with a payment rate of $12,500. However, on March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, the proposed payment for CPT code 0686T in CY 2024 would reflect payment for both the service that is performed and the device used each time it is reported on a claim.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are only two claims for CPT code 0686T within this time period. We note that 0686T was still designated as a Category A IDE study for these claims and therefore, the payment for these claims only included payment for the cost of the service. As the available claims data is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0686T as a low volume service under our universal low volume APC policy, and use the highest of the geometric mean cost, arithmetic mean cost, or median cost to assign CPT code 0686T to the appropriate New Technology APC. Based on the two available claims in CY 2022, when CPT code 0686T was still designated as a Category A IDE study, the geometric mean is estimated to be: $4,466; the median is estimated to be: $4,480; and the arithmetic mean is estimated to be: $4,480. Because $4,480 is the greatest of these methodologies, we would use this value to set the payment rate for CPT code 0686T. However, we have concerns that the available claims data and universal low volume APC policy calculations would not accurately capture the cost of the service following its approval as a Category B IDE study in March of 2023. If 0686T were still designated as a Category A IDE study, then the two claims available would be appropriate to set its payment rate, as the claims reflect the cost of the service and exclude the cost of the device. However, because CPT code 0686T was approved as a Category B IDE study, meaning Medicare coverage and payment of the device is no longer statutorily prohibited, the two CY 2022 claims available would not accurately capture the cost of 0686T for CY 2024.

Therefore, based on the service costs reflected in the available claims and our estimates of the cost of the Category B device, for CY 2024, we propose to maintain CPT code 0686T's current APC assignment. Specifically, we propose to assign CPT code 0686T to APC 1575 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50.

Please refer to Table 17 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0686T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

[8] ClinicalTrials.gov. ''The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER)(#HOPE4LIVER).'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/study/NCT04573881.*

TABLE 17: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1575

i. Liver Multiscan Service (APC 1505)

Effective July 1, 2021, CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session; single organ) and 0649T (Quantitative magnetic resonance for analysis of tissue composition (*e.g.,* fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) are associated with the Liver MultiScan service. LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. For CY 2023, we assigned CPT codes 0648T and 0649T to New Technology APC 1511 (New Technology—Level 11 ($901–$1,000) with a payment rate of $950.50.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. We identified only 39 claims each for CPT code 0648T and CPT code 0649T during this time period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0648T and 0649T to the appropriate New Technology APC. There are available claims data from CY 2021 and CY 2022 for CPT codes 0648T and 0649T. Our analysis of the data for CPT code 0648T found the geometric mean cost of the service is approximately $269, the arithmetic mean cost of the service is approximately $320, and the median cost of the service is approximately $313. Our analysis of the data for CPT code 0649T found the geometric mean cost of the service is approximately $102, the arithmetic mean cost of the service is approximately $136, and the median cost of the service is approximately $83. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT codes 0648T and 0649T. In accordance to our SaaS Add-on Codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the identical APCs and the same status indicator assignments as their standalone codes. Consistent with our SaaS Add-on Codes policy, CPT code 0649T, the add-on code for LiverMultiScan would be assigned to the identical APC and status indicator to CPT code 0648T, the standalone code for the same service. Therefore, we propose, for CY 2024, to assign CPT codes 0648T and 0649T to APC 1505 (New Technology—Level 5 ($301–$400)) with a payment rate of $350.50.

Please refer to Table 18 below for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0648T and 0649T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 18: FINAL CY 2023 AND PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511	S	1505
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511	S	1505

j. Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)

Prior to CY 2022, extracapsular cataract removal with insertion of intraocular lens was reported using CPT codes describing cataract removal alongside a CPT code for device insertion. Specifically, the procedure was described using CPT codes 66982 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification), complex, requiring devices or techniques not generally used in routine cataract surgery (for example, iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic developmental stage; without endoscopic cyclophotocoagulation) or 66984 (Extracapsular cataract removal with insertion of intraocular lens prosthesis (1-stage procedure), manual or mechanical technique (for example, irrigation and aspiration or phacoemulsification); without endoscopic cyclophotocoagulation) and 0191T (Insertion of anterior segment aqueous drainage device, without extraocular reservoir, internal approach, into the trabecular meshwork; initial insertion).

For CY 2022, the AMA's CPT Editorial Panel created two new Category I CPT codes describing extracapsular cataract removal with insertion of intraocular lens prosthesis, specifically, CPT codes 66989 (Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) and 66991 (Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more); deleted a Category III CPT code, specifically, CPT code 0191T, describing insertion of anterior segment aqueous drainage device; and created a new Category III CPT code, specifically, CPT code 0671T, describing anterior segment aqueous drainage device without concomitant cataract removal.

For CY 2022, we finalized the assignment of CPT codes 66989 and 66991 to New Technology APC 1563 (New Technology—Level 26 ($4,001–$4,500)). We stated that we believed that the change in coding for MIGS is

significant in that it changes longstanding billing for the service from reporting two separate CPT codes to reporting a single bundled code. Without claims data, and given the magnitude of the coding change, we explained that we did not believe we had the necessary information on the costs associated with CPT codes 66989 and 66991 to assign them to a clinical APC at that time. We maintained these APC assignments for CY 2023.

For CY 2023, the payment rates were based on claims data submitted between January 1, 2021, and December 31, 2021, and processed on or before June 30, 2022, and CCRs, if available. Because CPT codes 66989 and 66991 were effective January 1, 2022, and we had no claims data for CY 2022, we finalized continued assignment of CPT codes 66989 and 66991 to New Technology APC 1563.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. For CY 2024, based on our analysis of claims data, we found a total of 898 single frequency claims and an estimated geometric mean cost of $5,241.55 for CPT code 66989 and a total of 5,576 single frequency claims and an estimated geometric mean cost of $4,957.01 for CPT code 66991. Given the claims volume, we believe it is appropriate to reassign the service to a clinical APC using our regular process of using the most recent year of claims data for a procedure. Upon review, we determined that the most appropriate clinical APC family for CPT codes 66989 and 66991 would be the Intraocular Procedures APC family (APC 5491 through 5495). However, there was a large payment rate difference between the level 2 Intraocular Procedures APC (APC 5492), which has a payment rate of $3,970.62, and the level 3 Intraocular Procedures APC (APC 5493), which has a payment rate of $14,067.62. Assigning CPT codes 66989 and 66991 to either APC 5492 or 5493 would result in a payment rate that would not reflect the cost for these procedures.

Therefore, given the significant difference in payment between APC 5492 and APC 5493, we believe it is appropriate to restructure the Intraocular Procedures APC family. Specifically, we propose to create a sixth level in the Intraocular Procedures APC family by dividing APC 5492 into two APCs—an APC for services with a geometric mean cost of less than $5,000 and an APC for services with a geometric mean cost of greater than, or equal to, $5,000. We believe that the creation of an additional level in the Intraocular APC family will create a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. See section III.E. (OPPS APC-Specific Policies: Intraocular Procedures) of this proposed rule for a detailed discussion of our proposal to restructure the Intraocular Procedures APC family. Reorganizing the Intraocular Procedures APCs would create a proposed Level 3 APC to be referred to as ''Proposed APC 5493'' with a payment rate of approximately $5,110.58 which is closer to the geometric mean of CPT codes 66989 and 66991. We note that, although these services have different estimated geometric mean costs, interested parties have indicated that it is preferable that they be placed within the same APC due to clinical similarity; therefore, we propose to reassign CPT codes 66989 and 66991 to Proposed APC 5493 for CY 2024.

The proposed clinical APC and status indicator assignments for CPT codes 66989 and 66991 are found in Table 19. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule.

TABLE 19: CY 2023 FINAL AND CY 2024 PROPOSED OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 66989 AND 66991

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
66989	Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493
66991	Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (e.g., trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more	S	1563	S	5493

k. Scalp Cooling (APC 1514)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibration and fitting of the cap. CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves, for example, 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology—Level 20 ($1,801–$1,900)) with a payment rate of $1,850.50. For CY 2023, we did not have any claims data; so we continued to assign CPT code 0662T to APC 1520.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. The Scalp Cooling service became effective in the OPPS in CY 2022, and we have identified 11 single frequency paid claims for CPT code 0662T for CY 2022. As this is below the threshold of 100 claims for a service within a year, we propose to designate CPT code 0662T as a low volume service under our universal low volume APC policy and to use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, the geometric mean cost for CPT code 0662T is $831.16; the median is $797.63; and the arithmetic mean is $1,284.59. Therefore, for CY 2024, we propose to designate this service as a low volume service under our universal low volume APC policy and reassign CPT code 0662T to APC 1514 (New Technology—Level 14 ($1,201–$1,300)) with a payment rate of $1,250.50 for CY 2024 based on the arithmetic mean of $1,284.59.

Please refer to Table 20 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0662T. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 20: FINAL CY 2023 AND PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE SCALP COOLING PROCEDURE

CPT Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0662T	Scalp cooling, mechanical; initial measurement and calibration of cap	S	1520	S	1514

1. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (ct) tissue characterization, including interpretation and report, obtained with concurrent ct examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (*e.g.,* CT surveillance versus invasive procedure). For CY 2023, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology—Level 8 ($601–$700)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are no claims available for CPT codes 0721T and 0722T. Therefore, for CY 2024, we propose to continue assigning CPT codes 0721T and 0722T to New Technology APC 1508.

Please refer to Table 21 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS codes 0721T and 0722T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 21: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM LCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (ct) tissue characterization, including interpretation and report, obtained with concurrent ct examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

m. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (qmrcp), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (mri) examination of the same anatomy (*e.g.,* organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP Software as a medical Service (SaaS). The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. For CY 2023, we assigned CPT codes 0723T and 0724T to New Technology APC 1511 (New Technology—Level 11 ($900–$1,000)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. For CPT code 0723T, there were no claims during this time period. Because there are no claims available, we propose to continue to assign CPT code 0723T to New Technology APC 1511 with a payment rate of $950.50.

For CPT code 0724T, there was only one claim for CY 2022. As this is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0724T as a low volume service under our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to an appropriate New Technology APC. Because there is only one claim available, the geometric mean, arithmetic mean, and median costs are estimated to be $26 for this service. However, because there is only a single claim for CPT code 0724T, the single claim available appears to be an outlier based on the cost information we received from the manufacturer. Therefore, we have concerns that the universal low volume APC policy calculations do not accurately capture the cost of the service. Therefore, for CY 2024, we propose to continue assigning CPT code 0724T to New Technology APC 1511 with a payment rate of $950.50.

Please refer to Table 22 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code 0724T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 22: PROPOSED CY 2024 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (qmrcp), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (mri) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

n. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: The CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial [9] and the CardiAMP Cell Therapy Heart Failure Trial.[10] The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cells treatment for the following: (1) Patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology—Level 37 ($9,501–$10,000)) with the status indicator ''T.'' We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (*e.g.,* mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (*e.g.,* transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix transendocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology—Level 39 ($15,001–$20,000)) most accurately accounted for the resources associated with furnishing the procedure described by HCPCS code C9782.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are no available claims for ratesetting for CY 2024. Therefore, for CY 2024, we propose to continue assigning HCPCS code C9782 to New Technology APC 1590 with a payment rate of $17,050.50.

Please refer to Table 23 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9782 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

[9] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1.*

[10] *ClinicalTrials.gov.* ''Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure.'' Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT02438306.*

TABLE 23: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

o. Surfacer® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (*e.g.,* inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was established on October 1, 2021, and since its establishment the code has been assigned to New Technology APC 1534 (New Technology—Level 34 ($8,001–$8,500)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. Although HCPCS code C9780 was effective October 1, 2021, we have no claims data at this time. Because we have no claims data available, for CY 2024, we propose to continue to assign HCPCS code C9780 to APC 1534 with a proposed payment rate of $8,250.50.

Please refer to Table 24 below for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9780 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 24: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

p. Insertion or Replacement of Neurostimulator System for Treatment of Central Sleep Apnea; Complete System (APC 1580)

HCPCS code 0424T (Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator)) is associated with the use of the Remede® System, which is used to treat adult patients with moderate to severe Central Sleep Apnea. HCPCS code 0424T was first effective in January 1, 2016, and subsequently assigned to Comprehensive APC 5464 (Neurostimulator and Related Procedures APC—Level 4). For CY 2021, we created a 5-level structure for the Neurostimulator and Related Procedure

APC series, and consequently, assigned HCPCS code 0424T to the highest level in the series: Comprehensive APC 5465 (Neurostimulator & Related Procedures APC—Level 5). For CY 2023, we proposed to continue the 5-level structure for the Neurostimulator and Related Procedure APC series, while also soliciting comment on the creation of an additional Level 6 APC in the series. In the CY 2023 final rule with comment period, we finalized our proposal to continue the 5-level APC structure based on a determination that the existing structure remained appropriate based on clinical and cost characteristics. However, we also recognized that CPT code 0424T was not appropriately assigned to the Comprehensive APC 5465 based on a significant difference between its geometric mean cost and that of the APC. Therefore, for CY 2023, we finalized the assignment of HCPCS code 0424T to New Technology APC 1581 (New Technology—Level 44 ($50,001–$60,000)).

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are only 30 claims for HCPCS code 0424T available during this time period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign HCPCS code 0424T to the appropriate New Technology APC. Considering the available claims data for HCPCS code 0424T, the arithmetic mean is $49,468; the median is $48,285; and the geometric mean cost is $44,287. Of these, the arithmetic mean is the statistical methodology that estimates the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for New Technology APC 1580 (New Technology—Level 43 ($40,001–$50,000)) with a payment rate of $45,000.50. Therefore, for CY 2024, we propose to assign HCPCS code 0424T to New Technology APC 1580. We note that for the CY 2024 update, the CPT Editorial Panel is deleting HCPCS code 0424T and replacing it with placeholder code 3X008 effective January 1, 2024. Consequently, we propose to assign HCPCS code 0424T to status indicator ''D'' to indicate the code will be deleted and assigning its replacement code, specifically, placeholder code 3X008, to APC 1580 for CY 2024. For placeholder code 3X008, the final 5-digit CPT code number will be listed in the CY 2024 OPPS/ASC final rule with comment period.

Please refer to Table 25 below for the proposed OPPS New Technology APC and status indicator assignment for placeholder code 3X008 for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 25: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS 0424T/3X008

HCPCS Code	Long Descriptor	Final CY 2023 OPPS SI	Final CY 2023 OPPS APC	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0424T	Insertion or replacement of a neurostimulator system for treatment of central sleep apnea; complete system (transvenous placement of right or left stimulation lead, sensing lead, implantable pulse generator	S	1581	D	N/A
3X008	Insertion of phrenic nerve stimulator system (pulse generator and stimulating lead[s]), including vessel catheterization, all imaging guidance, and pulse generator initial analysis with diagnostic mode activation, when performed	N/A	N/A	S	1580

q. Cleerly Labs (APC 1511)

Cleerly Labs is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity using Atherosclerosis Imaging-Quantitative Computer Tomography (AI–QCT). This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic. angiography; data preparation and transmission, computerized analysis of

data, with review of computerized analysis output to reconcile discordant data, interpretation and report.

0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

In the CY 2021 OPPS/ASC final rule with comment period, we assigned the CPT codes 0623T, 06234T, 0625T, 0626T codes to status indicator ''E1'' to indicate that the codes are not payable by Medicare when submitted on outpatient claims because the service had not received FDA clearance at the time of the assignment.

For the October 2022 update, based on our review of the New Technology application submitted to CMS for OPPS payment consideration, we evaluated the current status indicator assignments for CPT codes 0623T–0626T. Based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors, we assigned CPT code 0625T to a separately payable status. Specifically, in the October 2022 OPPS Update CR (Change Request 12885, Transmittal 11594, dated September 9, 2022), we reassigned CPT code 0625T to status indicator ''S'' (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and APC 1511 (New Technology—Level 11 ($900–$1,000)) with a payment rate of $950.50, effective October 1, 2022, following our review of the manufacturer's New Technology APC application.

For CY 2024, the OPPS payment rates are proposed to be based on available CY 2022 claims data. There are 90 claims for CPT code 0625T during this time period. As this is below the threshold of 100 claims for a service within a year, we could propose to designate CPT code 0625T as a low volume service under our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately $3.70, the arithmetic mean cost to be approximately $4.10, and the median cost to be approximately $3.50. Under our universal low volume APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology—Level 1A (0–$10)) with a payment rate of $5.00. However, we acknowledge that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the claims available only reflect two months of data, we have concerns that we do not have sufficient claims data to justify reassignment to another New Technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 59902), for CY 2024 we propose to maintain CPT code 0625T's current assignment. Specifically, for CY 2024, we propose to continue to assign CPT code 0625T to New Technology APC 1511 with a payment rate of $950.50.

Please refer to Table 26 below for the proposed OPPS New Technology APC and status indicator assignment for CPT code 0625T for CY 2024. The proposed CY 2024 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 26: PROPOSED CY 2024 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CLEERLY LABS HCPCS CODE 0625T

HCPCS Code	Long Descriptor	Proposed CY 2024 OPPS SI	Proposed CY 2024 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	S	1511

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For this proposed rule, CY 2022 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2022 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or

brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to four years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for this proposed rule, we propose to designate five brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The five brachytherapy APCs and five clinical APCs meet our criteria of having fewer than 100 single claims in the claims year used for ratesetting (CY 2022 for this proposed rule). Eight of the ten APCs were designated as low volume APCs in CY 2023. Based on data for this CY 2024 OPPS/ASC proposed rule, APC 2642 (Brachytx, stranded, C–131) now meets our criteria to be designated a Low Volume APC; and we propose to designate it as such for CY 2024. Further, with the proposed addition of Level 6 Intraocular APC (APC 5496), as discussed in section III.E of this proposed rule, and the reassignment of certain intraocular procedures from Level 2 to Level 3, the Level 4 Intraocular APC (which was the Level 3 Intraocular APC in CY 2023), now meets our criteria to be designated a Low Volume APC; and we propose to designate it as such for CY 2024.

Table 27 includes the APC geometric mean cost without the low volume APC designation, that is, if we calculated the geometric mean cost based on CY 2022 claims data available for ratesetting; the median, arithmetic mean, and geometric mean cost using up to four years of claims data based on the APC's designation as a low volume APC; and the statistical methodology we propose to use to determine the APC's cost for ratesetting purposes for CY 2024. As discussed in our CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), given our concerns with CY 2020 claims data as a result of the PHE, the four years of claims data we proposed to use to calculate the costs for these APCs are CYs 2018, 2019, 2021, and 2022.

TABLE 27: COST STATISTICS FOR PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	$31.74	$61.83	$41.06	$61.83
2635	Brachytx, non-str, HA, P-103	21	$98.73	$58.38	$60.86	$54.77	$60.86
2636	Brachy linear, non-str, P-103	1	$89.34	$22.17	$57.15	$33.66	$57.15
2642	Brachytx, stranded, C-131	76	$99.92	$79.90	$100.65	$79.90	$100.65
2647	Brachytx, NS, Non-HDRIr-192	2	$452.28	$201.69	$403.29	$167.08	$403.29
5244	Level 4 Blood Product Exchanges and Related Services	55	$52,105.34	$45,729.50	$53,360.21	$44,947.25	$53,360.21
5494	Level 4 Intraocular Procedures	50	$13,410.30	$13,305.40	$14,227.94	$13,410.31	$14,227.94
5495	Level 5 Intraocular Procedures	88	$7,399.50	$16,660.19	$16,269.57	$12,817.68	$16,660.19
5496	Level 6 Intraocular Procedures	26	$11,183.21	$17,309.37	$15,981.28	$14,084.23	$17,309.37
5881	Ancillary Outpatient Services When Patient Dies	91	$7,701.96	$7,018.18	$13,576.10	$7,777.84	$13,576.10

* For this proposed rule, there are no CY 2022 claims that contain the HCPCS code assigned to APC 2632 that are available for CY 2024 OPPS/ASC ratesetting.

E. Proposed APC-Specific Policies: Intraocular Procedures

In reviewing the claims data available for the CY 2024 OPPS proposed rule, we believed that it was appropriate to create an additional Intraocular Procedures level, between the current Level 2 and 3 APCs. We last adjusted the number of APCs in the Intraocular Procedures family in CY 2020, when we reestablished APC 5495 (Level 5 Intraocular Procedures) to accommodate the procedure described by CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) based on its estimated cost (84 FR 61249 through 61250). Creating a new APC in the Intraocular Procedures family will allow for a smoother distribution of the costs between the different levels based on their resource costs and clinical characteristics. Therefore, for the CY 2024 OPPS, we propose to establish a six-level APC structure for the Intraocular Procedures series. We noted that in addition to creating the new level, we also proposed to assign CPT codes 66989 (Extracapsular cataract removal w/IOL insertion, complex; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) and 66991 (Extracapsular cataract removal w/IOL insertion; with insertion of intraocular (*e.g.,* trabecular meshwork, supraciliary, suprachoroidal) anterior segment aqueous drainage device, without extraocular reservoir, internal approach, one or more) to the new Level 3 APC, as discussed in further detail in section III.C.2.j. (Minimally Invasive Glaucoma Surgery (MIGS) (APC 5493)) of this proposed rule.

IV. Proposed OPPS Payment for Devices

A. Proposed Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years. Prior to CY 2017, our regulation at § 419.66(g) provided that this pass-through payment eligibility period began on the date CMS established a particular transitional pass-through category of devices, and we based the pass-through status expiration date for a device category on the date on which pass-through payment was effective for the category. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79654), in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category.

In addition, prior to CY 2017, our policy was to propose and finalize the dates for expiration of pass-through status for device categories as part of the OPPS annual update. This means that device pass-through status would expire at the end of a calendar year when at least 2 years of pass-through payments had been made, regardless of the quarter in which the device was approved. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79655), we changed our policy to allow for quarterly expiration of pass-through payment status for devices, beginning with pass-through devices approved in CY 2017 and subsequent calendar years, to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices. We also have an established policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.[11]

In the CY 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 15 device categories eligible for pass-through payment. These devices are listed in Table 28 of this proposed rule where we detail the expiration dates of pass-through payment status for each of the 15 devices currently receiving device pass-through payment.

In the CY 2022 OPPS/ASC final rule with comment period we used CY 2019 claims data, rather than CY 2020 claims data, to inform CY 2022 ratesetting (86 FR 63755). As a result, we utilized our equitable adjustment authority at section 1833(t)(2)(E) of the Act to provide up to four quarters of separate payment for 27 drugs and biologicals and one device category whose pass-through payment status expired between December 31, 2021 and September 30, 2022 to mimic continued pass-through payment, promote adequate access to innovative therapies for Medicare beneficiaries, and gather sufficient data for purposes of assigning these devices to clinical APCs (86 FR 63755). A full discussion of this finalized policy is included in section X.F of the CY 2022 OPPS/ASC final rule with comment (86 FR 63755).

Section 4141(a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328) amended section 1833(t)(6) by adding a new subparagraph (K), which extended the device pass-through status under paragraph (6) for a 1-year period beginning January 1, 2023, for device categories whose period of pass-through status would have ended on December 31, 2022. There are five device categories for which pass-through status would have ended on December 31, 2022, but which will now end on December 31, 2023. Pass-through status began for these device categories on January 1, 2020.

[11] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act (PRA). This collection (CMS–10052) has an OMB control number of 0938–0857 and an expiration date of November 30, 2025.

TABLE 28: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN THE FOURTH QUARTER OF 2023, IN 2024, OR IN 2025

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1824*	Generator, cardiac contractility modulation (implantable)	1/1/2020	12/31/2023
C1982*	Catheter, pressure-generating, one-way valve, intermittently occlusive	1/1/2020	12/31/2023
C1839*	Iris prosthesis	1/1/2020	12/31/2023
C1734*	Orthopedic/device/drug matrix for opposing bone-to-bone or soft tissue-to bone (implantable)	1/1/2020	12/31/2023
C2596*	Probe, image-guided, robotic, waterjet ablation	1/1/2020	12/31/2023
C1052	Hemostatic agent, gastrointestinal, topical	1/1/2021	12/31/2023
C1062	Intravertebral body fracture augmentation with implant (e.g., metal, polymer)	1/1/2021	12/31/2023
C1825	Generator, neurostimulator (implantable), nonrechargeable with carotid sinus baroreceptor stimulation lead(s)	1/1/2021	12/31/2023
C1761	Catheter, transluminal intravascular lithotripsy, coronary	7/1/2021	6/30/2024
C1831	Personalized, anterior and lateral interbody cage (implantable)	10/1/2021	9/30/2024
C1832	Autograft suspension, including cell processing and application, and all system components	1/1/2022	12/31/2024
C1833	Monitor, cardiac, including intracardiac lead and all system components (implantable)	1/1/2022	12/31/2024
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	1/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	1/1/2023	12/31/2025
C1747	Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)	1/1/2023	12/31/2025

*Device for which pass-through status was extended for a 1-year period by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117-328), titled Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID-19.

2. New Device Pass-Through Applications for CY 2024

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of

Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance and FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;
- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and
- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;
- Have an average cost that is not ''insignificant'' relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and
- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

Beginning in CY 2016, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly subregulatory process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 annual rulemaking process, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html,* in the ''Downloads'' section. In addition, CMS is amenable to

meeting with applicants or potential applicants to facilitate information sharing to support the evaluation of an OPPS device pass-through payment application or discuss general application criteria, including the substantial clinical improvement criterion.

b. Applications Received for Device Pass-Through Status for CY 2024

We received six complete applications by the March 1, 2023 quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this proposed rule. We received three of the applications in the second quarter of 2022, one of the applications in the third quarter of 2022, no applications in the fourth quarter of 2022, and two of the applications in the first quarter of 2023. One of the applications was approved for device pass-through status during the quarterly review process: MY01 Continuous Compartmental Pressure Monitor, which was submitted on May 31, 2022 and conditionally approved as HCPCS code C1834 on October 1, 2022. However, after further review, we determined that the conditional approval was in error, and consequently, we deleted code C1834 on March 31, 2023.

Applications received for the later deadlines for the remaining 2023 quarters (the quarters beginning June 1, September 1, and December 1 of 2023), if any, will be discussed in the CY 2025 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf.*

Discussions of the applications we received by the March 1, 2023 deadline are included below.

(1) Alternative Pathway Device Pass-Through Applications

We received two device pass-through applications by the March 2023 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore are eligible to apply under the alternative pathway.

(a) CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath

Phillips North America, LLC submitted an application for a new device category for transitional pass-through payment status for CavaClear Inferior Vena Cava (IVC) Filter Removal Laser Sheath (CavaClear) for CY 2024. Per the applicant, CavaClear is a breakthrough device intended for tissue ablation in the removal of embedded IVC filters that have failed a previous retrieval method. IVC filters are used to capture blood clots and prevent them from moving to the lungs in patients with venous thromboembolism. Per the applicant, research has shown that IVC filters may have long-term complications, including device migration, filter fracture, and IVC occlusion; as a result, FDA issued a safety notice that recommends that physicians remove retrievable IVC filters as soon as they are no longer needed. The applicant stated that CavaClear facilitates the detachment of firmly adherent IVC filters using ultraviolet laser energy. The applicant explained that CavaClear uses circumferential tissue ablation that can aid in capturing the filter within seconds of laser activation, which can help increase physician efficiency, and may help lower costs by reducing the number of retrieval attempts to remove an embedded IVC filter.

According to the applicant, CavaClear is a 14F or 16F laser catheter used for the intra-operative removal of IVC filters. The applicant further explained that CavaClear consists of optical fibers arranged in a circle, sandwiched between inner and outer polymer tubing. The fibers terminate at the distal end within a polished tip and at the proximal end within a coupler that mates with the excimer laser. According to the applicant, inner and outer stainless-steel bands, which form a radiopaque marker, protect the optical fibers at the distal tip. The applicant also stated that CavaClear was designed to slide through an introducer sheath and with an inner lumen to allow an appropriate traction platform to pass through it. Per the applicant, the device facilitates detachment of IVC filters from the IVC wall using ultraviolet laser energy and subsequent collapse of the filter, partially within the laser sheath and entirely within the introducer sheath. The laser sheath was designed for use with the CVX–300® Excimer Laser or Philips Laser System (PLS), which allows the multifiber laser sheaths to transmit ultraviolet energy to the tissue at the distal tip of the device. The applicant further explained that, when activated, the laser ablates the tissue and frees the IVC filter from overgrowth in a controllable fashion. The applicant stated that by using cool ultraviolet laser energy around the embedded IVC filter, CavaClear can assist in fast filter capture with low force.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), CavaClear received FDA Breakthrough Device designation effective April 23, 2021, for the ablation of tissue in the removal of IVC filters that have failed a previous retrieval method. FDA granted the applicant De Novo classification for CavaClear (laser-powered IVC filter retrieval catheter) on December 21, 2021, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CavaClear on May 30, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether CavaClear meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, CavaClear is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient through the insertion of a laser catheter temporarily for the interoperative removal of IVC filters as required at § 419.66(b)(3).

We are inviting public comment on whether CavaClear meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant also claimed that CavaClear meets the criterion because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We are inviting public comment on whether CavaClear meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of

December 31, 1996. The applicant described CavaClear as an IVC filter removal device that uses a laser to ablate tissue and is intended to facilitate detaching and removing indwelling IVC filters. Per the applicant, CavaClear is the first and only FDA-cleared solution for advanced IVC filter removal, and the applicant claimed that no previous device categories for pass-through payment appropriately describe CavaClear. Per the applicant, the possible existing pass-through code—HCPCS code C2629 (Introducer/sheath, other than guiding, other than intracardiac electrophysiological, laser)—does not appropriately describe CavaClear because CavaClear uses a unique laser mechanism of action, unlike the snag, snare, and forcep method to remove IVC filters; CavaClear is not intended to remove pacemaker and defibrillator leads like the products described by C2629; and CavaClear impacts different anatomy than the products described by C2629. Specifically, the applicant asserted that C2629 includes devices that are indicated to remove implanted pacemaker and defibrillator leads and devices via a catheter inserted into the vascular system. In addition, the applicant noted that FDA granted CavaClear De Novo classification, reflecting that there is no legally marketed predicate device for CavaClear.

We note, based on the description the applicant provided, that CavaClear is a laser sheath intended for use in the IVC, which is not intracardiac, and thus could be encompassed by the descriptor of C2629. We also note that another existing pass-through payment category may appropriately describe CavaClear. Specifically, we believe that C1773 (Retrieval device, insertable (used to retrieve fractured medical devices)) may appropriately describe CavaClear. Pass-through payment category C1773 is a broad category descriptor for a device that retrieves another device within a patient's vascular system. Based on the description the applicant provided, CavaClear is a device (a laser-powered sheath that uses a laser to ablate tissue in the IVC) used to retrieve another medical device (an IVC filter device), which is consistent with the descriptor for C1773. In this context, we believe CavaClear may be similar to the devices currently described by C2629 and C1773, and therefore, CavaClear may also be appropriately described by C2629 and C1773.

We are inviting public comment on whether CavaClear meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device is included in the category that has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body party compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. CavaClear has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation, and therefore, appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine if the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of cost significance requirements. The applicant stated that CavaClear would be reported with HCPCS code listed in Table 29.

TABLE 29: HCPCS CODE REPORTED WITH CAVACLEAR

HCPCS Code	Long Descriptor	SI	APC
37193	Retrieval (removal) of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J1	5183

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5183, which had a CY 2022 payment rate of $2,923.63 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 37193 had a device offset amount of $762.48 at the time the application was received.[12] According to the applicant, the cost of CavaClear is $3,165.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $3,165.00 for CavaClear is 108.26 percent of the applicable APC payment amount for the service related to the category of devices of $2,923.63 (($3,165.00/$2,923.63) × 100 = 108.26 percent). Therefore, we

[12] We note that the applicant selected a value of $537.36 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 37193 in APC 5183 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060). We selected the value of $762.48, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of $762.48 would result in CavaClear meeting the cost significance requirement.

believe CavaClear meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $3,165 for CavaClear is 415.09 percent of the cost of the device-related portion of the APC payment amount for the related service of $762.48 (($3,165.00/$762.48) × 100 = 415.09 percent). Therefore, we believe CavaClear meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $3,165.00 for CavaClear and the portion of the APC payment amount for the device of $762.48 is 82.18 percent of the APC payment amount for the related service of $2,923.63 ((($3,165.00 − 762.48)/$2,923.63) × 100 = 82.18 percent). Therefore, we believe that CavaClear meets the third cost significance requirement.

We are inviting public comment on whether CavaClear meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) CERAMENT® G

BONESUPPORT AB submitted an application for a new device category for transitional pass-through payment status for CERAMENT® G for CY 2024. Per the applicant, CERAMENT® G is a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant further explained that CERAMENT® G is an adjunct to systematic antibiotic therapy as part of the surgical treatment of osteomyelitis (*i.e.,* bone infection) in the extremities and is used where there is a need for supplemental bone void filler material. The applicant asserted that CERAMENT® G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing and augment provisional hardware to help support bone fragments during the surgical procedure. The applicant stated that CERAMENT® G is the first on-label solution for a one-stage surgical approach to treating bone infections with its unique dual mode of action: (1) promote bone healing (bone remodeling), and (2) protect bone healing (elution of a local broad-spectrum antibiotic). According to the applicant, once implanted, CERAMENT® G resorbs overtime and remodels into bone in 6 to 12 months.

Per the applicant, CERAMENT® G is comprised of three key compounds: (1) hydroxyapatite (HA), (2) calcium sulfate (CaS), and (3) gentamicin sulfate. According to the applicant, by combining calcium sulfate and hydroxyapatite, a balance is achieved between implant resorption rate and bone remodeling rate. The applicant further explained that the CaS acts as a resorbable carrier for HA. The applicant described that HA has a slow resorption rate and high osteoconductivity promoting bone remodeling and thus gives long-term structural support to the newly-formed bone. The gentamicin sulfate is a broad-spectrum aminoglycoside antibiotic that is sensitive to a spectrum of aerobic bacteria, particularly gram-negative bacilli, as well as aerobic gram-positive cocci, in particular Staphylococcus aureus, some coagulase negative staphylococci (CoNS) (*e.g.,* Staphylococcus epidermidis), and some strains of streptococci. According to the applicant, the gentamicin sulfate is present in the bone void filler to prevent colonization from gentamicin-sensitive microorganisms to protect bone healing.

Per the applicant, CERAMENT® G is comprised of eight components (these components contain the three key compounds as well as other parts for the successful application of CERAMENT® G): (1) CERAMENT® CMI, a closed mixing injection system pre-packed with ceramic bone substitute (CBS), is a mixture of the CaS (60 wt percent) and HA (40 wt percent). The applicant further explained that the mixing device is comprised of a 60 mL syringe, which in its proximal part is equipped with a movable combined plunger and mixing paddle, and in its distal part with a luer-lock connection. The movable mixing paddle allows effective mixing of the material inside the syringe. Calcium Sulfate and Hydroxyapatite (CSH) are the setting component of the bone void filler, and per the applicant, this component will react to calcium sulfate dihydrate (CSD) and will be resorbed over time, giving place for natural bone to grow into the bone graft. The applicant described that CSD is added as a seeding agent to accelerate the setting reaction of CSH to CSD, and that HA is an osteoconductive mineral similar to natural bone (this part of the bone graft substitute will not be resorbed and does not need to be surgically removed). The applicant stated that CSH and CSD conform to specifications based on the monograph Calcium Sulfate Dihydrate 0982, European Pharmacopoeia (EP) and the Official Monograph for Calcium Sulfate U.S. Pharmacopoeia/National Formulary (USP) as well as internal requirements; (2) CERAMENT® ID, an injection device used to inject the paste into the bone void or gap; (3) Valve, a needleless valve needed for the transfer of the ceramic paste from the CERAMENT® CMI to the CERAMENT® ID; (4) Tip Extenders, which are sterile, plastic needles with an inner diameter of 2.55 mm and two lengths (50 and 100 mm), that are connected to the CERAMENT® ID to facilitate placement of the paste at the debridement site; (5) CERAMENT® GENTAMICIN, the gentamicin sulfate in a glass vial equipped with a stopper and a cap. The gentamicin sulfate subcomponent has a potency equivalent to ≥590μg gentamicin/mg (anhydrous substance) and is dissolved in the 0.9 percent sterile sodium chloride solution and mixed with the CBS powder. Per the applicant, the prepared paste sets to a calcium sulfate dihydrate matrix with embedded hydroxyapatite particles, and gentamicin sulfate. The applicant further explained that it delivers 17.5 mg gentamicin per mL paste. Per the applicant, the gentamicin sulfate subcomponent complies with the EP monograph for gentamicin sulfate; (6) CERAMENT® MIXING LIQUID, a sterile sodium chloride, (NaCl) solution, 9 mg per mL in a glass vial. Per the applicant, it is the liquid component of CERAMENT® G. This component contains water which is needed for the calcium sulfate reaction to occur. The liquid meets requirements of the compendial excipient of USP/EP grade and is also registered in the inactive ingredient database; (7) BONESUPPORT DP, which includes two ventilated dispensing pins to facilitate easy handling when preparing the gentamicin solution; and (8) BONESUPPORT SYRINGE, a single packed, sterile 10 mL syringe with a male/female rotator assembly, and is used when preparing the gentamicin solution.

According to the applicant, after the surgical site has been prepared and any dead bone is debrided (*i.e.,* removed),

the CERAMENT® G paste is prepared by the surgeon or surgical technician by: (1) mixing the gentamicin powder with the provided saline to make a gentamicin liquid; (2) adding the gentamicin liquid to the powder in the CERAMENT® CMI syringe and mixing the gentamicin liquid and powder; and (3) transferring the resulting paste to a smaller delivery syringe. Four minutes after the start of mixing, the paste is ready to be used as a bone void filler. Per the applicant, it can be injected using the tip extenders provided in the kit or by attaching a needle to the delivery syringe, or it can be placed into a bead mold to form beads. Fifteen minutes after the start of mixing, CERAMENT® G can be drilled into, if required. At 20 minutes, it is fully set, at which time the wound can be closed.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), CERAMENT® G received FDA Breakthrough Device designation effective March 12, 2020, as a resorbable, gentamicin-eluting ceramic bone graft substitute intended for use as a bone void filler as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis. By eluting gentamicin, CERAMENT® G can inhibit the colonization of gentamicin-sensitive microorganisms to protect bone healing. CERAMENT® G can augment provisional hardware to help support bone fragments during the surgical procedure and is resorbed and replaced by bone during the healing process. FDA granted the applicant De Novo classification for CERAMENT® G under the generic name, resorbable calcium salt bone void filler containing a single approved aminoglycoside antibacterial substance on May 17, 2022, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for CERAMENT® G on May 31, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether CERAMENT® G meets the newness criterion at § 419.66(b)(1).

With respect to the integral part of the service criterion at § 419.66(b)(3), the applicant did not indicate whether CERAMENT® G is integral to the service provided. However, per the applicant, CERAMENT® G is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted into the patient as required at § 419.66(b)(3).

We are inviting public comment on whether CERAMENT® G meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CERAMENT® G is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if CERAMENT® G is a supply or material furnished incident to a service.

We are inviting public comment on whether CERAMENT® G meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described CERAMENT® G as a single-use implantable bone void filler combination device/drug that remodels into bone and elutes gentamicin. The applicant asserted that there are no existing bone void filler devices cleared or approved for use in the U.S. for single stage surgical reconstruction of bone defects that provide stability, promote bone formation, and effectively support the surgical treatment of infection by antibiotic elution. However, for comparison purposes, the applicant listed HCPCS code C1734 (Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable)), as a device category that it considers similar to CERAMENT® G's device category.[13]

The applicant stated that CERAMENT® G differs from the bone substitutes AUGMENT® and AUGMENT® Injectable (devices described by HCPCS code C1734). We note that CMS approved an application for AUGMENT® Bone Graft as a new device category for transitional pass-through payment status and established HCPCS code C1734 as a new device category beginning in CY 2020. We refer readers to the CY 2019 OPPS/ASC final rule with comment period (84 FR 61292 through 61294) for a full discussion of the AUGMENT® Bone Graft application and decision.[14] The applicant asserted that CERAMENT® G and AUGMENT® differ in terms of the product composition and mechanism of action, or intended use. In addition, the applicant asserted that the products are intended for different groups of patients. With respect to composition, per the applicant, CERAMENT® G consists of HA, CaS, and gentamicin sulfate. In contrast, the applicant stated that AUGMENT® consists of beta-tricalcium phosphate (β-TCP) and recombinant human platelet-derived growth factor (rhPDGF–BB), and AUGMENT® Injectable consists of β-TCP, rhPDGF–BB, and a collagen matrix. With respect to the mechanism of action, the applicant stated that CaS in CERAMENT® G acts as a resorbable carrier for HA, which has a slow resorption rate and high osteoconductivity, providing a scaffold for new bone generation. The applicant further explained that by combining CaS and HA, a balance is achieved between implant resorption rate and bone remodeling rate, and by eluting gentamicin, CERAMENT® G can reduce the recurrence of chronic osteomyelitis from gentamicin-sensitive microorganisms to protect bone healing. In contrast, according to the applicant, the rhPDGF–BB in AUGMENT® acts as a chemo-attractant and mitogen for cells involved in wound healing and through its promotion of angiogenesis at the site of healing, and the β- TCP acts as a bone void filler to prevent soft tissue from collapsing into the void.

Per the applicant, CERAMENT® G is indicated for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. In contrast, per the applicant, AUGMENT® and AUGMENT® Injectable[15] are indicated

[13] HCPCS code C1734 is a device category for which pass-through status was extended for a 1-year period beginning January 1, 2023, by section (a)(2) of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328), titled Extension of Pass-Through Status Under the Medicare Program for Certain Devices Impacted by COVID–19. *https://www.cms.gov/files/document/r11801cp.pdf*

[14] *https://www.govinfo.gov/content/pkg/FR-2019-11-12/pdf/2019-24138.pdf*

[15] The applicant differentiates itself from AUGMENT® and AUGMENT® Injectable, but does not use the term ''AUGMENT® Bone Graft'' in the application. However, the link provided in the application goes to the AUGMENT® web page that describes AUGMENT® Regenerative Solutions, AUGMENT® Bone Graft and AUGMENT® Injectable. We use the term ''AUGMENT®'' to collectively refer to the AUGMENT® products described herein and those listed on the AUGMENT® website. The applicant provided web page (in footnote): AUGMENT BONE GRAFT website: *http://www.augmentbonegraft.com/healthcare-professionals/*.

for use as an alternative to autograft in arthrodesis in patients who require a bone fusion, such as patients who have arthritis, avascular necrosis, joint instability or deformity, or joint arthroplasty of the ankle and/or hindfoot. Further, the applicant asserted that AUGMENT® cannot be used in the patients for whom CERAMENT® G is indicated because AUGMENT® is specifically contraindicated in patients with an active infection at the operative site.

We note that, based on the description of the device provided by the applicant, CERAMENT® G and AUGMENT® differ in terms of composition and intended use, but also note that device categories are not intended to be device specific. Rather, device categories are intended to encompass any device that can be appropriately described by the category. As such, when we evaluate a potential pass-through device to determine whether it meets the device category criterion at § 419.66(c)(1), we compare the subject device to the device category descriptor rather than to the specific device for which the device category was created. Specifically, C1734 describes any device that meets the following descriptor: Orthopedic/device/drug matrix for opposing bone-to-bone or soft-tissue-to-bone (implantable), and per the applicant, CERAMENT® G is described as an implantable device/drug matrix that, with its intended use, will oppose soft-tissue-to-bone. In this context, we believe CERAMENT® G may be similar to the devices currently described by C1734, and therefore CERAMENT® G may also be appropriately described by C1734.

We are inviting public comment on whether CERAMENT® G meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. CERAMENT® G has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the discussion of the newness criterion) and therefore appears to meet the criterion at § 419.66(c)(2)(ii) and is not evaluated for substantial clinical improvement.

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that CERAMENT® G would be reported with HCPCS codes listed in Table 30.

BILLING CODE 4120–01–P

TABLE 30: HCPCS CODES REPORTED WITH CERAMENT® G

HCPCS Code	Long Descriptor	SI	APC
21510	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), thorax	**	**
23035	Incision, bone cortex (e.g., osteomyelitis or bone abscess), shoulder area	J1	5112
23170	Sequestrectomy (e.g., for osteomyelitis or bone abscess), clavicle	J1	5113
23172	Sequestrectomy (e.g., for osteomyelitis or bone abscess), scapula	**	**
23174	Sequestrectomy (e.g., for osteomyelitis or bone abscess), humeral head to surgical neck	**	**
23180	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), clavicle	J1	5114
23182	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), scapula	J1	5114
23184	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), proximal humerus	J1	5114
23935	Incision, deep, with opening of bone cortex (e.g., for osteomyelitis or bone abscess), humerus or elbow	J1	5113
24134	Sequestrectomy (e.g., for osteomyelitis or bone abscess), shaft or distal humerus	J1	5114
24136	Sequestrectomy (e.g., for osteomyelitis or bone abscess), radial head or neck	**	**
24138	Sequestrectomy (e.g., for osteomyelitis or bone abscess), olecranon process	J1	5114
24140	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), humerus	J1	5113
24145	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), radial head or neck	J1	5114
24147	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis), olecranon process	J1	5113
25035	Incision, deep, bone cortex, forearm and/or wrist (e.g., osteomyelitis or bone abscess)	J1	5114
25150	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); ulna	J1	5113
25151	Partial excision (craterization, saucerization, or diaphysectomy) of bone (e.g., for osteomyelitis); radius	J1	5113
26230	Partial excision (craterization, saucerization, or diaphysectomy) bone (e.g., osteomyelitis); metacarpal	J1	5113
26992	Incision, bone cortex, pelvis and/or hip joint (e.g., osteomyelitis or bone abscess)	**	**

HCPCS Code	Long Descriptor	SI	APC
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); superficial	**	**
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (e.g., osteomyelitis or bone abscess); deep (subfascial or intramuscular) abscess); deep (subfascial or intramuscular)	**	**
27303	Incision, deep, with opening of bone cortex, femur or knee (e.g., osteomyelitis or bone abscess)	**	**
27360	Partial excision (craterization, saucerization, or diaphysectomy) bone, femur, proximal tibia and/or fibula (e.g., osteomyelitis or bone abscess)	J1	5113
27607	Incision (e.g., osteomyelitis or bone abscess), leg or ankle	J1	5113
27640	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); tibia	J1	5113
27641	Partial excision (craterization, saucerization, or diaphysectomy), bone (e.g., osteomyelitis); fibula	J1	5113
28005	Incision, bone cortex (e.g., osteomyelitis or bone abscess), foot	J1	5113
28120	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); talus or calcaneus	J1	5113
28122	Partial excision (craterization, saucerization, sequestrectomy, or diaphysectomy) bone (e.g., osteomyelitis or bossing); tarsal or metatarsal bone, except talus or calcaneus	J1	5113

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060).

BILLING CODE 4120–01–C

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5112, which had a CY 2022 payment rate of $1,422.51 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 23035 had a device offset amount of $217.36 at the time the application was received. We note that the applicant submitted cost information for two different device sizes (5 ml and 10 ml) for CERAMENT® G. Per the applicant, the average patient will require approximately 10 ml per procedure, with a weighted cost of $7,567.00 per patient.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $7,567.00 for CERAMENT® G is 531.95 percent of the applicable APC payment amount for the service related to the category of devices of $1,422.51 (($7,567.00/$1,422.51) × 100 = 531.95 percent). Therefore, we believe CERAMENT® G meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,567.00 for CERAMENT® G is 3,481.32 percent of the cost of the device-related portion of the APC payment amount for the related service of $217.36 (($7,567.00/$217.36) × 100 = 3,481.32 percent). Therefore, we believe that CERAMENT® G meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,567.00 for CERAMENT® G and the portion of the APC payment amount for the device of $217.36 is 516.67 percent of the APC payment amount for the related service of $1,422.51 ((($7,567.00 − $217.36)/$1,422.51) × 100 = 516.67 percent). Therefore, we believe

that CERAMENT® G meets the third cost significance requirement.

We are inviting public comment on whether the CERAMENT® G meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(2) Traditional Device Pass-Through Applications

(a) Ambu® aScopeTM 5 Broncho HD

Ambu Inc. submitted an application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD for CY 2024. Per the applicant, the Ambu® aScope™ 5 Broncho HD is one component of the Ambu® aScope™ 5 Broncho HD System which consists of: (1) the Ambu® aScope™ 5 Broncho HD (5.0/2.2 or 5.6/2.8), a sterile, single-use, disposable flexible/rigid bronchoscope; and (2) Ambu® aBox™ 2, a compatible, reusable display unit. The applicant is only seeking a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD component.

Per the applicant, the Ambu® aScope™ 5 Broncho HD, consists of: (1) a handle, to hold the scope (designed for left and right hand); (2) a control lever, to move the distal tip up or down in a single plane; (3) a working channel and working channel port, for instillation of fluids and insertion of endotherapy instruments; (4) a biopsy valve, to be attached to the working channel port, for insertion of endotherapy instruments or attachment of a syringe; (5) a suction connector, for connection of suction tubing; (6) a suction button, to activate suction when pressed; (7) endoscope buttons 1 and 2 (depending on settings in display unit the two remote switches allow for direct activation on handle of four different functionalities such as image and video capturing, initiate advanced red contrast (ARC), and zoom); (8) a rotation control ring, for rotation of the insertion cord during procedure; (9) a tube connection, for fixation of tubes with standard connector during procedure; (10) an insertion cord and insertion portion, flexible airway insertion cord; (11) bending section, maneuverable part; (12) distal tip, which contains the camera, light source (two light-emitting diodes (LEDs)), and the working channel exit; (13) display unit connector, to connect to the port on the Ambu® aBox™ 2 display unit; (14) a cable, to transmit the image signal to the Ambu® aBox™ 2 display unit; (15) a protective handle cover, to protect the control lever during transport and storage; (16) a protective pipe, to protect the insertion cord during transport and storage; and (17) an introducer, to facilitate introduction of luer lock syringes.

The applicant stated that the Ambu® aScope™ 5 Broncho HD is an imaging/illumination bronchoscope device that uses an integrated camera module and built-in dual LED illumination to provide access to, and imaging of, the lungs for diagnostic and therapeutic purposes for pulmonology patients. The device is intended for endoscopy and endoscopic surgery within the lungs, also known as bronchoscopy. According to the applicant, the Ambu® aScope™ 5 Broncho HD was designed to perform a wide array of diagnostic and interventional pulmonology procedures. The applicant noted that the Ambu® aScope™ 5 Broncho HD is a single-use bronchoscope designed to be used with the Ambu® aBox™ 2 display unit, endotherapy instruments, and other ancillary equipment for bronchoscopic procedures and examination within the airways and the tracheobronchial tree. It is intended to provide visualization via the compatible display unit, the Ambu® aBox™ 2, and to allow passage of endotherapy instruments via its working channel.

Per the applicant, the Ambu® aScope™ 5 Broncho HD bronchoscope is inserted into the patient airway through either the mouth, nose, or via a tracheostomy, if present. The applicant explained that when the Ambu® aScope™ 5 Broncho HD bronchoscope has reached the correct position, endotherapy instruments can be inserted into the working channel system of the bronchoscope. Per the applicant, an introducer supplied with the bronchoscope can be attached to the working channel port via a luer lock adaptor, while the bronchoscope is in use. The applicant noted that the suction system may be used to remove blood, saliva, and mucus from the airway. The applicant indicated that a bronchoscope operator monitors the field of view via the integrated camera of the Ambu® aScope™ 5 Broncho HD bronchoscope and the procedure is finished when the device is pulled out completely.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on July 25, 2022, the applicant received 510(k) clearance from FDA for the Ambu® aScope™ 5 Broncho HD as a device to be used for endoscopic procedures and examination within the airways and tracheobronchial tree. We received the application for a new device category for transitional pass-through payment status for the Ambu® aScope™ 5 Broncho HD on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, the Ambu® aScope™ 5 Broncho HD is integral to the service provided, is used for one patient only, comes in contact with human tissue, and is surgically inserted as required by § 418.66(b)(3).

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether the Ambu® aScope™ 5 Broncho HD is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, or if the Ambu® aScope™ 5 Broncho HD is a supply or material furnished incident to a service.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described the Ambu® aScope™ 5 Broncho HD as a single-use, disposable, digital flexible/rigid bronchoscope that is used in pulmonary procedures (bronchoscopy) to diagnose and treat conditions of the lungs, including tumors or bronchial cancer, airway blockage (obstruction), narrowed areas in airways (strictures), inflammation, and infections such as tuberculosis (TB), pneumonia, fungal or parasitic lung infections, interstitial pulmonary disease, causes of persistent cough, causes of coughing up blood, spots seen on chest X-rays, and vocal cord paralysis. The applicant claimed that the Ambu® aScope™ 5 Broncho HD is different from other endoscopes because it is a single-use endoscope indicated

for use in the respiratory system, the device records snapshots or video of images, and the device is temporarily inserted into the patient airway to diagnose and treat lung problems. According to the applicant, there are two possible existing pass-through device categories, represented by the following codes: C1748 (Endoscope, single-use (*i.e.,* disposable), upper gastrointestinal tract (GI), imaging/illumination device (insertable)); and C1747 (Endoscope, single-use (*i.e.,* disposable), urinary tract, imaging/illumination device (insertable)). The applicant noted that while these two codes are for single-use endoscopic devices, they are only appropriate for GI and urinary tract imaging, respectively. Therefore, the applicant asserted that these two codes would not apply to a single-use, disposable, bronchoscopy for use in pulmonary procedures. We note that while C1748 and C1747 are intended to be used in different anatomical areas of the patient, the codes for both device categories describe devices that are single use and have imaging capabilities.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the Ambu® aScope™ 5 Broncho HD represents a substantial clinical improvement over existing technologies by: (1) elimination of complex cleaning/reprocessing procedures, (2) reduction of microbial transmission and infection since it is single-use, (3) elimination of the need for continuous training of reprocessing staff, (4) minimization of the risk of patient cross-contamination, (5) assurance that a sterilized scope will be used each time, and (6) assurance that there will be no biofilm from endoscope channels. The applicant provided four articles, an FDA guidance letter, and an FDA safety notice specifically for the purpose of addressing the substantial clinical improvement criterion.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates complex cleaning/reprocessing procedures because it is a single-use device, the applicant referenced an FDA Reprocessing Final Guidance document [16] issued March 17, 2015. This FDA document provides guidance to medical device manufacturers on the complex activities involved in crafting and validating reprocessing instructions that ensure that the device can be used safely and for the purpose for which it is intended. The guidance document is limited to reusable medical devices and single-use medical devices that are initially supplied as non-sterile to the user and require the user to process the device prior to its use. In this guidance document, FDA identifies a subset of reusable medical devices (including bronchoscopes and accessories) that pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed and indicates design features which may pose a challenge to adequate reprocessing for arthroscopes, laparoscopic instruments, and electrosurgical instruments, and their respective accessories. However, the FDA guidance does not mention sterile, single-use medical devices in this document.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD reduces microbial transmission and infection because it is single-use, the applicant referenced an FDA safety notice [17] issued on September 17, 2015 (2015 FDA safety notice). The FDA notice discussed the findings of an investigation into infections associated with reprocessed reusable medical devices, including an analysis of Medical Device Reports (MDRs) submitted to FDA from manufacturers and health care facilities. The notice provided that between January 2010 and June 2015, FDA received 109 MDRs concerning infections or device contamination associated with flexible bronchoscopes. However, FDA noted that, when compared to the number of bronchoscopy procedures performed in the U.S. each year, this is considered a small number of MDRs. In 2014, FDA received 50 MDRs that mentioned infections or device contamination associated with reprocessed flexible bronchoscopes, which prompted additional investigation of this issue. FDA indicated that a small number of the reported infections were from persistent device contamination despite following the manufacturer's reprocessing instructions, however, most of the infections were the result of the failure to meticulously follow manufacturer instructions for reprocessing, or continued use of devices despite integrity, maintenance, and mechanical issues. FDA provides additional recommendations for health care facilities and staff that reprocess flexible bronchoscopes and patients considering bronchoscopy procedures, but does not reference single-use bronchoscopes in the notice.

In support of its claim that the use of the Ambu® aScope™ 5 Broncho HD eliminates the need for continuous training of reprocessing staff, the applicant referenced a study by Châteauvieux et al.,[18] which assessed the organizational and economic impacts of the introduction of a single-use flexible bronchoscope (FB) (Ambu® aScope™, versions 2 and 3) in comparison with a reusable FB (Pentax®) at the hospital level. The study took place between May 2016 and October 2016 in the Georges Pompidou European Hospital, an 800-bed university hospital in France. Châteauvieux et al. noted that the introduction of single-use FBs led to a more simplified process, less stress for medical and paramedical staff in emergency situations, teaching benefits, and easier management of transport, in comparison with reusable FBs. However, the authors recommended limiting the use of single-use FBs to specific situations, and to prioritize the use of reusable devices for most of the bronchoscopies for cost savings.

The applicant referred to a meta study by Barron and Kennedy[19] to support its

[16] FDA Guidance March 17 2015 ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff'' *https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf.*

[17] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[18] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[19] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy,*

claim that the use of Ambu® aScope™ 5 Broncho HD minimizes the risk of patient cross-contamination, ensuring that health care providers have taken optimal steps to safeguard their patients. Barron and Kennedy summarized the major advantages of single-use FBs over the standard reusable FBs in clinical scenarios. The authors noted that single-use FBs offer a safer alternative to standard reusable FBs in specific scenarios where reduced risk of cross infection was critical in the immunocompromised patient and in rare cases of prior contamination due to transmissible spongiform encephalopathies.

The applicant referred to a self-sponsored study [20] by Ofstead et al.[21] in 2019, in support of its claim that the use of the Ambu® aScope™ 5 Broncho HD ensures a sterilized scope is available for each procedure while reusable endoscopes may not be sterile even if manufacturers' cleaning protocols are followed. The study first referenced Ofstead et al.'s 2017 [22] evaluation of the effectiveness of bronchoscope processing in three large hospitals where every bronchoscope had visible defects, protein was detected on 100 percent of high-level disinfected bronchoscopes, and bacteria or mold were found on 58 percent of the patient-ready bronchoscopes. Then, in 2019, Ofstead et al. conducted the study to determine the time and cost of acquiring, maintaining, and reprocessing bronchoscopes in four hospitals (two in the Midwest and two in the West Coast). Three hospitals had obtained single-use Ambu® bronchoscopes (2018, version unspecified) for procedures done in certain departments, after hours, or in emergency situations. Per Ofstead et al. (2019), the cost for procedures with reusable bronchoscopes ($281 to $803) were comparable or higher than the cost of single-use bronchoscopes ($220 to $315), due to acquisition and maintenance of large inventories of bronchoscopes to ensure real-time availability for various hospital departments. Ofstead et al. (2019) suggested the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities. Ofstead et al. (2019) summarized the steps that can be taken to reduce risks related to bronchoscope contamination and to focus on implementing quality management systems to improve personnel competence, bronchoscope inventory management, maintenance, reprocessing effectiveness, and storage. In addition to following manufacturer's steps for reprocessing the devices, Ofstead et al. (2019) suggest the use of single-use bronchoscopes and accessories for after hours and emergency situations and any procedures that do not require advanced bronchoscopy capabilities, which are currently available in the list of recommendations.

The applicant referenced a review article by Kovaleva et al.[23] in support of its claim that the Ambu® aScope™ 5 Broncho HD's single-use feature is free of biofilm from endoscope channels since routine cleaning procedures do not remove biofilm reliably from endoscope channels. This review presents an overview of the infections and cross-contaminations related to flexible gastrointestinal endoscopy and bronchoscopy and illustrates the impact of biofilm on endoscope reprocessing and post-endoscopic infection. Kovaleva et al. noted that the use of antibiofilm-oxidizing agents with an antimicrobial coating inside washer disinfectors could reduce biofilm build-up inside endoscopes and automated endoscope re-processors and decrease the risk of transmitting infections.[24] Per Kovaleva et al. while sterilization can be helpful to destroy microorganisms within biofilms, ethylene oxide sterilization may fail in the presence of organic debris after an inadequate cleaning procedure before reprocessing of flexible endoscopes. There was no mention of single-use bronchoscopes in the study.

The applicant cited a self-sponsored, laboratory study by Kurman et al.,[25] in general support of its application. Kurman et al. evaluated and assessed four different manufacturers' single-use flexible bronchoscopes (SFB), including the nominated device and its prior model, against their reusable flexible bronchoscopes (RFB) on a cadaver (*i.e.,* corpse) model, benchtop fixturing, and artificial plastic lung model. The study compared the Ambu® aScope™ 5 Broncho HD with four devices: (1) Olympus H-SteriScope; (2) Verathon BFLEX; (3) Boston Scientific Exalt-B; and (4) Ambu® aScope™ 4 Broncho (the prior model of the nominated device). The study concluded that the Ambu® aScope™ 5 Broncho HD has the highest overall performance, the highest overall rating for sampling, and highest maneuverability in difficult segmental airways among the comparator devices.

The applicant indicated that the Ambu® aScope™ 5 Broncho HD differs from these comparator devices as it is the only device that is compatible with argon gas plasma coagulation, cryotherapy, and laser, with an HD (1200x800) chip, has more degrees of articulation with tools, and provides image and video capture from the scope handle with multiple programmable functions including capture photo, start/end video, enable zoom, and initiate ARC. In addition, the applicant stated that the nominated device is superior to its earlier legally marketed device in terms of maneuverability into difficult segmental airways, overall performance, and overall sampling assessment. The applicant asserted that the nominated device differs from the predicate device due to a rotation mechanism on the handle and its superior articulation, which allow for more complicated procedures to be performed such as cryotherapy and coagulation. The applicant stated that the nominated device is equipped with an HD image chip and increased depth-of-field and field-of-view, which allow interventional pulmonologists to perform inspections, biopsies, and debulking. The applicant also stated that the nominated device's programmable buttons allow for superior documentation than the earlier bronchoscope device.

We note that the nominated device was determined to be substantially equivalent to the earlier device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices share similar technological characteristics such as optical system, bending section, diameter of insertion cord and distal

37(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[20] Ofstead et al. acknowledged that this study was supported by an unrestricted research grant from Ambu Inc. The study sponsor did not participate in designing the study, identifying sites, collecting data, compiling results, interpreting the findings, or writing this article.

[21] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[22] Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest. 2018;154(5):1024–34.

[23] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clinical microbiology reviews, 26(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[24] Kovaleva, J., Peters, F.T., van der Mei, H.C., & Degener, J.E. (2013). Transmission of infection by flexible gastrointestinal endoscopy and bronchoscopy. Clinical microbiology reviews, 26(2), 231–254. *https://doi.org/10.1128/CMR.00085-12.*

[25] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

end, and insertion portion length. Furthermore, the 510(k) summary indicated that both have the same technical characteristics, which include maneuverable tip controlled by the user, flexible insertion cord, camera and LED light source at the distal tip, sterilized by ethylene oxide, single-use devices, ability for aspiration and sample collection in bronchoalveolar lavage, and bronchial wash procedures.

We note that in its application, the applicant provided a comparison of certain devices or device categories that it believed are most closely related or similar to the Ambu® aScope™ 5 Broncho HD. The applicant identified six reusable devices that it believed are most closely related: (1) Olympus Evis Exera Iii Bronchovideoscope Bf–h190; (2) Pentax EB–J10 Video Bronchoscope; (3) Fujifilm EB–580S Video Bronchoscope; (4) Olympus BF–Q190; (5) Olympus BF–1TH190; and (6) Olympus BF–XT190. According to the applicant, these devices are used during the same specific procedure(s) and/or services with which the Ambu® aScope™ 5 Broncho HD is used. The applicant stated that the Ambu® aScope™ 5 Broncho HD's single-use feature is unique among the comparators. According to the applicant, the single-use feature eliminates bronchoscope reprocessing. The applicant further submitted several articles reporting results on the prevalence of infection due to incomplete or inadequate processing for reusable bronchoscopes, which we summarize as follows. An article by Shimizu et al.[26] concluded that patients with larger lesions, presence of endobronchial lesions, histology of small-cell lung cancer, and advanced-disease stage tended to develop pulmonary infectious complications more often than other patients. A 2020 systematic literature review and meta-analysis by Travis et al.[27] reported an estimated average reusable FB cross-contamination rate of 8.69 percent ± 1.86 (standard division [SD]) (95 percent confidence interval [CI]: 5.06–12.33 percent) among eight studies from the U.S. and four European countries. Travis et al.[28] attributed the infection rate to the differences in the study design and sampling methods, geography, low number of data points, clinical settings, and an aversion towards publishing negative findings among the eight studies. Furthermore, the applicant submitted a 2019 systematic review and cost-effective analysis by Mouritsen et al.,[29] which reported an average 2.8 percent cross-contamination rate from reusable, flexible bronchoscopes among 16 studies from the United Kingdom, U.S., France, Spain, Australia, and Taiwan. Mouristen et al. identified that the single-use flexible bronchoscopes were cost effective and associated with a reduction of infection risk of approximately 1.71–4.07 percent compared with reusable flexible bronchoscopes. Lastly, the applicant again cited the meta study by Barron and Kennedy [30] referencing the findings from Ofstead et al.[31], the review by Mouristen et al., and the Emergency Care Research Institute's (ECRI's) report.[32] Of note, ECRI highlighted the recontamination of flexible endoscopes due to mishandling or improper storage as one of the top 10 health technology hazards.

Based on the evidence submitted with the application, we note the following concerns: We are concerned about whether the Ambu® aScope™ 5 Broncho HD can be distinguished from similar devices on the market and the earlier versions of the nominated device on the market sufficiently to demonstrate substantial clinical improvement. Four of the studies the applicant submitted, Châteauvieux et al.,[33] Barron and Kennedy,[34] Kurman et al.,[35] and Ofstead et al.,[36] investigated and provided data on the applicant's earlier models of the device, but did not provide comparisons to the nominated device. In addition, we note that the studies provided also did not compare the nominated device to an appropriate comparator such as a single-use bronchoscope from a different manufacturer or a standard reusable bronchoscope in a clinical setting. In addition, we note that the applicant's self-sponsored study by Kurman, et al.[37] was conducted in the laboratory (*i.e.,* on cadaver, benchtop fixturing, and artificial plastic lung) and not in the clinical setting. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care.

Furthermore, we note that the Châteauvieux et al.[38] and Barron and Kennedy [39] studies suggested limiting the use of single-use bronchoscope device to specific situations (*i.e.,* after hours or emergency), immunocompromised patients, and in rare cases of preventing prior contamination in the inpatient setting. We believe that further investigation with comparators in these specified cases would be particularly helpful to determine whether the device demonstrates substantial clinical improvements over currently available

[26] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. *Nagoya journal of medical science, 82*(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[27] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention,* 17571774231158203.

[28] Id.

[29] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[30] Barron, S. P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[31] Ofstead CL, Quick MR, Wetzler HP, et al. Effectiveness of reprocessing for flexible bronchoscopes and endobronchial ultrasound bronchoscopes. Chest. 2018;154(5):1024–34.

[32] ECRI. Top 10 health technology hazards. Executive brief. Pennsylvania: ECRI Institute, Health devices; 2019. p. 2019.

[33] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[34] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[35] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

[36] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[37] Kurman, J., Wagh, A., Benn, B., & Islam, S., (2023). A Comparison of Single-use Bronchoscopes and Reusable Bronchoscopes for Interventional Pulmonology Applications. Confidential. Ambu Inc., funded evaluation and testing.

[38] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[39] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

treatments in the clinical setting where it is most likely to be used.

We note concern that the application and all the articles submitted as evidence of substantial clinical improvement discuss potential adverse events from reusable bronchoscope procedures, but do not directly show any clinical improvement that results from the use of the Ambu® aScope™ 5 Broncho HD. We note that Shimizu et al.,[40] Travis et al.,[41] Barron and Kennedy,[42] and Ofstead et al.[43] provided information about the risks associated with reprocessing reusable devices and reported mixed results.

We also note that the 2015 FDA safety notice[44] provided preliminary information regarding infections associated with the use of reprocessed flexible bronchoscopes, but did not discuss or recommend the use of disposable, single-use devices in the notice. Furthermore, we note the following concerns about studies on the prevalence of infection due to incomplete/inadequate reprocessing of reusable bronchoscopes. The studies authored by Châteauvieux *et al.*,[45] Shimizu et al.,[46] Travis et al.,[47] and Mouritsen et al.[48] have small sample sizes. Furthermore, the Barron and Kennedy,[49] Travis et al.,[50] and Mouritsen et al.[51] studies used different study designs and sampling methodologies, or were performed in various clinical settings other than outpatient, which may affect the quality and reliability of the data provided in support of the applicant's assertions. We do not believe that we have sufficient information on the prevalence of infection to evaluate the applicant's substantial clinical improvement claims for the nominated device. We are seeking comments on the prevalence of infection due to incomplete/inadequate processing for bronchoscopes in the U.S. and whether single-use bronchoscopes reduce the infection rate in patients to identify the extent of the problem with existing technologies.

The applicant provided evidence which seemed to rely on indirect inferences from other sources of data. We question the relevance of the 2015 FDA safety notice[52] to the nominated device because as stated above, the guidance applies to reprocessed flexible bronchoscopes broadly, but not to disposable, single-use devices comparable to the nominated device. We are concerned that many of the applicant's substantial clinical improvement claims rely on an assumption that inadequate reprocessing of reusable bronchoscopes is positively correlated with heightened risk of infection, providing studies with small sample sizes and other limitations as described above as their only support. We note that the applicant provided background information on the established reprocessing guidelines[53] for reusable devices; however, the existence of reprocessing guidelines does not provide evidence on the prevalence of infection rates, establish a relationship between infection risk and reprocessing procedures, or substantiate that single-use disposable scopes, or the nominated device specifically, would be a substantial clinical improvement over currently available treatments.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that the Ambu® aScope™ 5 Broncho HD would be reported with HCPCS codes listed in Table 31.

BILLING CODE 4120–01–P

[40] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. Nagoya journal of medical science, 82(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[41] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention, 17571774231158203.*

[42] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[43] Ofstead, C.L., Hopkins, K.M., Eiland, J.E., & Wetzler, H.P. Managing Bronchoscope Quality and Cost: Results of a Real-world Study. *https://www.ambu.com/Files/Files/Ambu/Investor/News/English/2019/Managing%20Bronchoscope%20cost%20a%20real%20world%20study.pdf.*

[44] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[45] Châteauvieux, C., Farah, L., Guérot, E., Wermert, D., Pineau, J., Prognon, P., Borget, I., & Martelli, N. (2018). Single-use flexible bronchoscopes compared with reusable bronchoscopes: Positive organizational impact but a costly solution. *Journal of evaluation in clinical practice, 24*(3), 528–535. *https://doi.org/10.1111/jep.12904.*

[46] Shimizu, T., Okachi, S., Imai, N., Hase, T., Morise, M., Hashimoto, N., Sato, M., & Hasegawa, Y. (2020). Risk factors for pulmonary infection after diagnostic bronchoscopy in patients with lung cancer. Nagoya journal of medical science, 82(1), 69–77. *https://doi.org/10.18999/nagjms.82.1.69.*

[47] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. *Journal of Infection Prevention, 17571774231158203.*

[48] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia, 75*(4), 529–540.

[49] Barron, S.P., & Kennedy, M.P. (2020). Single-Use (Disposable) Flexible Bronchoscopes: The Future of Bronchoscopy? *Advances in therapy, 37*(11), 4538–4548. *https://doi.org/10.1007/s12325-020-01495-8.*

[50] Travis, H.S., Russell, R.V., & Kovaleva, J. (2023). Cross-contamination rate of reusable flexible bronchoscopes: A systematic literature review and meta-analysis. Journal of Infection Prevention, *17571774231158203.*

[51] Mouritsen, J.M., Ehlers, L., Kovaleva, J., Ahmad, I., & El-Boghdadly, K. (2020). A systematic review and cost effectiveness analysis of reusable vs. single-use flexible bronchoscopes. *Anaesthesia*, 75(4), 529–540.

[52] FDA Safety Communications, Infections Associated with Reprocessed Flexible Bronchoscopes: FDA Safety Communication, issued September 17, 2015. *https://www.fdanews.com/ext/resources/files/09-15/092115-safety-notice.pdf?1442508647.*

[53] FDA Guidance March 17, 2015, ''Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff.''

TABLE 31: HCPCS CODES REPORTED WITH THE AMBU® ASCOPE™ 5 BRONCHO HD

HCPCS Code	Long Descriptor	SI	APC
31615	Tracheobronchoscopy through established tracheostomy incision	T	5162
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing	J1	5153
31623	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with brushing or protected brushings	J1	5153
31624	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial alveolar lavage	J1	5153
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with bronchial or endobronchial biopsy(s), single or multiple sites	J1	5153
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of fiducial markers, single or multiple	J1	5155
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), single lobe	J1	5154
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration biopsy(s). Trachea, main stem and/or lobar bronchus(i)	J1	5154
31630	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with tracheal/bronchial dilation or closed reduction of fracture	J1	5154
31631	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of tracheal stent(s) (includes tracheal/bronchial dilation as required	J1	5155
31634	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with balloon occlusion, with assessment of air leak, with administration of occlusive substance (e.g., fibrin glue), if performed	J1	5155
31635	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of foreign body	J1	5153
31636	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of bronchial stent(s)(includes tracheal/bronchial dilation as required), initial bronchus	J1	5155
31638	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)	J1	5155
31640	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with excision of tumor	J1	5154
31641	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with destruction of tumor or relief of stenosis by any method other than excision (e.g., laser therapy, cryotherapy)	J1	5154

HCPCS Code	Long Descriptor	SI	APC
31643	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with placement of catheter(s) for intracavitary radioelement application	J1	5153
31645	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, initial	J1	5153
31646	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with therapeutic aspiration of tracheobronchial tree, subsequent, sams hospital stay	T	5152
31647	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with balloon occlusion, when performed, assessment of air leak, airway sizing, and insertion of bronchial valve(s), initial lobe	J1	5155
31648	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), initial lobe	J1	5154
31652	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration(s)/biopsy[ies]), one or two mediastinal and/or hilar lymph node stations or structures	J1	5154
31653	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration(s)/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stations or structures	J1	5154
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J1	5155
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J1	5155
31785	Excision of tracheal tumor or carcinoma; cervical	J1	5165
32400	Biopsy, pleura, percutaneous needle	J1	5072
32550	Insertion of indwelling tunneled pleural catheter with cuff	J1	5341
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	J1	5182
32552	Removal of indwelling tunneled pleural catheter with cuff	Q2	5181
32554	Thoracentesis, needle or catheter, aspiration of the pleural space; without imaging guidance	T	5181
31627	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with computer-assisted, image-guided navigation	**	N/A
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial lung biopsy(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with transbronchial needle aspiration	**	N/A

HCPCS Code	Long Descriptor	SI	APC
	biopsy(s), each additional lobe (list separately in addition to code for primary procedure)		
31637	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, each additional major bronchus stented (list separately in addition to code for primary procedure)	**	N/A
31649	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with removal of bronchial valve(s), each additional lobe (list separately in addition to code for primary procedure)	**	N/A
31654	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s)	**	N/A
31780	Excision tracheal stenosis and anastomosis; cervical	**	N/A
31781	Excision tracheal stenosis and anastomosis; cervicothoracic	**	N/A
31786	Excision of tracheal tumor or carcinoma; thoracic	**	N/A
32200	Pneumonostomy, with open drainage of abscess or cyst	**	N/A
32674	Thoracoscopy, surgical; with mediastinal and regional lymphadenectomy (List separately in addition to code for primary procedure)	**	N/A
32815	Open closure of major bronchial fistula	**	N/A

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060).

BILLING CODE 4120–01–C

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5152, which had a CY 2022 payment rate of $383.33 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note that the HCPCS code 31646 identified by the applicant had a device offset amount of $0.00 at the time the application was received. Accordingly, we are evaluating the cost significance requirements using $0.00 as the appropriate device offset amount. According to the applicant, the cost of the Ambu® aScope™ 5 Broncho HD is $799.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD is 208.44 percent of the applicable APC payment amount for the service related to the category of devices of $383.33 (($799.00/$383.33) × 100 = 208.44 percent). Therefore, we believe the Ambu® aScope™ 5 Broncho HD meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). Given that there are no device-related costs in the APC payment amount, and the Ambu® aScope™ 5 Broncho HD has an estimated average reasonable cost of $799.00, we believe that the Ambu® aScope™ 5 Broncho HD meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $799.00 for the Ambu® aScope™ 5 Broncho HD and the portion of the APC payment amount for the device of $0.00 exceeds the APC payment amount for the related service of $799.00 by 208.44 percent ((($799.00 − $0.00)/$383.33) × 100 = 208.44 percent). Therefore, we believe that the Ambu® aScope™ 5 Broncho HD meets the third cost significance requirement.

We are inviting public comment on whether the Ambu® aScope™ 5 Broncho HD meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(b) Praxis Medical CytoCore

Praxis Medical, LLC submitted an application for a new device category for transitional pass-through payment status for Praxis Medical CytoCore (CytoCore) for CY 2024. Per the applicant, CytoCore is a single-use disposable biopsy instrument. Per the

applicant, at the time of biopsy, the motorized CytoCore device contains gears and an internal motor that spins a minimally invasive needle to increase cellular yields in fewer passes. The applicant further explained that CytoCore is vacuum-assisted and can easily be operated using one hand. According to the applicant, the primary use is for biopsy of any suspicious thyroid nodule.

The applicant stated that the CytoCore Biopsy Instrument device package includes: (1) five CytoCore Biopsy Instruments, each containing three luer adapters in a sterile pouch, a syringe-holding device, equipped with a scissor-slide mechanism for drawing back the syringe plunger to create suction, an internal motor that rotates a needle, and an internal alkaline type battery; (2) five 5-mL syringes; and (3) instructions for use (IFU) booklets. Per the applicant, the CytoCore is compatible with disposable needles of 22-to-25-gauge and 4-to-10-cm length that are intended for soft tissue biopsy procedures (needles are not included in the device package). The applicant further explained that only the CytoCore luer adapters and syringes provided by Praxis can be used on CytoCore and that the CytoCore luer adapters can only be used with the CytoCore Biopsy Instrument.

Per the applicant, the operator of CytoCore can direct the needle and draw back the plunger with only one hand, thereby diminishing the need to move the needle in an in-and-out motion to harvest cells. As with other types of biopsies, the sample collected can help make a diagnosis or rule out conditions such as cancer. The applicant claimed that CytoCore enables the physician to collect more cellular material in fewer passes and reduce the number of repeat biopsies and surgeries related to inadequate cellular samples using the standard fine needle aspiration (FNA) biopsy. According to the applicant, CytoCore is designed to collect enough DNA for pathology to definitively rule in or out cancer and inform subsequent treatment at the time of the first biopsy. Per the applicant, studies report nondiagnostic rates for thyroid biopsies to be as high as 30 to 50 percent using standard FNA biopsy.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on March 31, 2020, the applicant received 510(k) clearance from FDA for CytoCore for use as a device to hold a syringe for performing a biopsy of an identified mass with one hand. We received the application for a new device category for transitional pass-through payment status for CytoCore on August 31, 2022, which is within 3 years from the date of the initial FDA marketing authorization.

We are inviting public comments on whether CytoCore meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant did not assert whether CytoCore is integral to the service provided. According to the applicant, CytoCore is used for one patient only. Per the applicant, CytoCore comes into contact with human tissue and is surgically inserted via the syringe attached to the motorized CytoCore device. Per the applicant, CytoCore is used with a 22-to-25-gauge standard fine needle (not included in the device package), which is inserted into human tissue to collect cellular samples. The applicant stated that the fine needle is attached to CytoCore, inserted into the nodule, and cellular material is collected through the needle into the syringe. The applicant further explained that the cellular material is visible in the hub of the needle or the luer adapter. However, we note that the motorized CytoCore device itself is not surgically implanted or inserted (either permanently or temporarily) or applied in or on a wound or other skin lesion, as required at § 419.66(b)(3). Further, we note that according to the FDA 510(k) Summary and Indication for Use, CytoCore is a device to hold a syringe for performing a biopsy of an identified mass with one hand and that the device never comes in contact with the patient. With respect to the exclusion criterion at § 419.66(b)(4), the applicant did not address whether CytoCore is equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets. The applicant also did not address whether CytoCore is a supply or material furnished incident to a service. However, in the CY 2000 OPPS interim final rule with comment period (65 FR 67798, 65 FR 67804 through 67805), we explained how we interpreted § 419.43(e)(4)(iv). We stated that we consider a device to be surgically implanted or inserted if it is surgically inserted or implanted via a natural or surgically created orifice, or inserted or implanted via a surgically created incision. We also stated that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted. We consider items used to create incisions, such as scalpels, electrocautery units, biopsy apparatuses, or other commonly used operating room instruments, to be supplies or capital equipment not eligible for transitional pass-through payments. We stated that we believe the function of these items is different and distinct from that of devices that are used for surgical implantation or insertion. Finally, we stated that, generally, we would expect that surgical implantation or insertion of a device occurs after the surgeon uses certain primary tools, supplies, or instruments to create the surgical path or site for implanting the device. In the CY 2006 OPPS final rule with comment period (70 FR 68516, 70 FR 68629 and 68630), we adopted as final our interpretation that the surgical insertion or implantation criterion can be met by devices that are surgically inserted or implanted via a natural or surgically created orifice, as well as those devices that are inserted or implanted via a surgically created incision. We reiterated that we maintain all of the other criteria in § 419.66 of the regulations, namely, that we do not consider an item used to cut or otherwise create a surgical opening to be a device that is surgically implanted or inserted.

We are inviting public comments on whether CytoCore meets the exclusion criterion at § 419.66(b).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described CytoCore as a motorized, single-use disposable biopsy instrument that contains gears and an internal motor that spins a minimally invasive needle during biopsy to increase cellular yields in fewer passes. Per the applicant, no previous device categories for pass-through payment have encompassed the device.

We have not identified an existing pass-through payment category that describes CytoCore. We are inviting public comment on whether CytoCore meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an

illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that the use of CytoCore results in substantial clinical improvement over existing technologies by: (1) reducing tissue trauma, bleeding; (2) increasing cellular harvest; (3) reducing passes required, clinical invasiveness; and (4) reducing nondiagnostic biopsy results follow up. The applicant provided one article and one conference poster in support of these claims.

In support of the claims that using CytoCore reduced tissue trauma and/or bleeding, and that it increased cellular harvest, the applicant submitted a conference poster of a study performed to evaluate the consistency and diagnostic quality of cellular material obtained with a 22-to-25-gauge fine needle using CytoCore as compared to FNA without using CytoCore and to traditional core biopsy. In the study,[54] samples utilizing FNA syringe (n = 14) and core biopsy (n = 12) were obtained and compared to biopsy samples obtained with CytoCore. The samples were analyzed in pathology separately for diagnostic adequacy. Using the Fisher exact test statistic, the study authors found no significant difference ($p < .05$) between FNA and CytoCore. Similarly, using the Fisher exact test statistic, the study authors found no significant difference ($p < .05$) between core biopsy and CytoCore. Specifically, the study authors reported that CytoCore was successful in obtaining a diagnosis in 78 percent of biopsies, which was unchanged from FNA; however, the authors reported that the cellular yield of samples obtained with CytoCore were superior to FNA biopsy samples. The study authors also reported that when compared to traditional core samples, CytoCore specimens were similar to traditional core biopsy in yielding a diagnosis, with CytoCore yielding a diagnosis 99 percent of the time and core biopsy 100 percent of the time. The authors concluded that CytoCore provides a reliably high amount of cellular material with significantly less tissue damage, which is especially useful for vascular tissue such as lymph nodes and breast tissue.

In support of the claims that using CytoCore reduces the number of passes required and the clinical invasiveness of a thyroid biopsy, and that it reduces nondiagnostic biopsy results and follow-up, the applicant provided an unpublished article that described the performance of CytoCore on the number of passes required to obtain an adequate sample and diagnostic biopsy in comparison to using traditional ultrasound-guided FNA (US–FNA) biopsy rates reported in the literature.[55] The study authors performed a retrospective chart review of consecutive US–FNA thyroid biopsies performed with CytoCore between August 2020 and March 2021. The chart records included ultrasound and pathology data points, including exam code, name of operator, biopsy tool, number of passes required for adequacy, and pathological diagnosis using the Bethesda System for Reporting Thyroid Cytopathology. The authors stated that the study included a total of 100 FNA biopsies from 69 patients, and a total of nine different operators performed these biopsies. At the time of biopsy, most (88 percent) of the patients were women, and, on average, were 65 years of age at the time of biopsy. In addition, the study authors stated that the number of nodules biopsied ranged from one to three on average, but most patients (65 percent) had only one nodule biopsied. The operators' years of experience ranged from 4 to 39 years of practice, with most (76 percent) performed by an operator with 5 years of practice experience (the study authors noted that this operator was never the sole operator for the procedure). In addition, a cytotechnologist was present for all procedures and rapid on-site evaluation (ROSE) was done on the smears to determine if the sample met the criteria for adequacy. All biopsies were performed using a 25 gauge, 1½ inch BD™ needle attached to CytoCore. The Bethesda System classification categories include Category I (nondiagnostic), Category II (benign), Category III (atypia), Category IV (suspicious for neoplasm), Category V (suspicious for malignancy), and Category VI (malignant). The study authors defined determinant diagnoses as the sum total of biopsies classified in Categories II (benign) and IV (malignant). The authors compared their study results to 20 published articles with publication dates between 2012 and 2022 that reported results for thyroid US–FNA biopsy. The study used descriptive statistics (averages and frequencies) and a single sample proportion test to compare the adequacy of the biopsy sample for each pass and the percentage of nondiagnostic, indeterminant, and determinant diagnosis classifications to conventional US–FNA techniques results reported in literature. According to the study authors, the number of passes required to attain an adequate sample using CytoCore ranged from one to four and was statistically significantly lower than using conventional FNA technique as reported in the 20 articles. Specifically, to obtain an adequate sample of a thyroid nodule using CytoCore compared to the conventional FNA technique, 65 percent required only one pass compared to 36 percent, 93 percent required two or fewer passes compared to 60 percent, 97 percent required three or fewer passes compared to 72 percent, and 100 percent required four or fewer passes compared to 75 percent, respectively. The authors stated that restricting the analyses to only one nodule per patient did not result in a change in significance. In addition, the authors stated that for their study group, pathology was able to make a determinant diagnosis (Category II and Category VI) for 91 percent of the samples. Specifically, of the 100 samples included in the study, 3 percent were nondiagnostic (Category I), 88 percent were benign (Category II), 4 percent were atypia (Category III), 2 percent were suspicious for neoplasm (Category IV), 0 percent were suspicious for malignancy (Category V), and 3 percent were malignant (Category VI). According to the authors, this was significantly better than the median nondiagnostic (Category I) and determinant diagnosis rates reported in the literature, 10% ($p = 0.02$) and 65% ($p < 0.001$), respectively. The rate of indeterminant classifications (Category III) was also lower in their study population but was not statistically significant ($p = 0.17$). The study authors concluded that if their study sample of 100 thyroid biopsies using CytoCore had the same median results as FNA thyroid biopsies reported in the literature, an additional 11 patients would have a

[54] Rey, E., Huber, J., Risam, R., Shahzad, R., Gonzalez, A., Acosta, A. (2022, April). Making the Diagnosis: Increasing the Cellular Yield of Pathology Samples Through a Motorized Rotating, Aspirating Device. Poster presented at the Daniel Manganaro Memorial 2022 Annual Scientific Poster Symposium, Elmira, NY. Retrieved from *https://www.arnothealthgme.org/_files/ugd/c76666_083113203de449a8a6054cf7b81aac82.pdf.*

[55] Authors unknown. Motorized rotating fine needle biopsy device reduces number of passes needed for cytological adequacy and improves diagnostic accuracy, not published; uses a retrospective study type.

biopsy classified as Category I or Category III (nondiagnostic and atypia) and would have required at least one more US–FNA to make a diagnosis, and an additional four patients would have a biopsy classified as Category IV (suspicious neoplasm) and would have required a partial lobectomy to determine malignancy. The study authors further concluded that in addition to the higher cost associated with additional biopsies and/or surgical intervention, there may be a greater impact on a patient's quality of life due to potential surgical complications, vocal cord palsy (VCP), lifetime hormonal replacement, and cosmetic scarring. Furthermore, the authors concluded that CytoCore resulted in more than a three-fold decrease in nondiagnostic (Category III) biopsies and significant increase in definitive diagnoses. The management of an initially indeterminant biopsy can range from a repeat US–FNA (Categories I and III) to lobectomy or thyroidectomy (Categories IV and V). The actual risk of malignancy can be as low as 1 percent to 15 percent for Categories I and III, but as high as 75 percent for Category V. Therefore, the authors concluded that initially indeterminant diagnosis can result in unnecessary procedures and increased costs for the healthcare system and patients for false positives, but for true malignancies, indeterminant biopsies could also delay diagnosis and treatment.

We note that the nominated device was determined to be substantially equivalent to a legally marketed device, the TAO Aspirator and Plastic Finger. The FDA 510(k) summary indicated that the devices share similar technological characteristics such as a device to hold a syringe for performing fine needle aspiration, a needle is connected to the syringe and inserted into a lesion, and a syringe plunger is retracted to create suction. The FDA 510(k) summary indicated that CytoCore differs in that a battery powers a motor that rotates the needle. In addition, the applicant provided a comparison of certain devices that it believed are most closely related or similar to CytoCore. Specifically, the applicant identified two devices with related HCPCS procedure codes that it believes are most closely related to CytoCore: (1) HCPCS code 10005 (fine needle aspiration biopsy, including ultrasound guidance, first lesion) and the Benton [sic] DickinsonTM (BDTM) device; and (2) HCPCS code 60100 (biopsy thyroid, percutaneous core needle) and the BioPince device. According to the applicant, the BDTM is a single-use 25-gauge 1-inch basic needle with no syringe and is the standard fine needle used most often in thyroid biopsy procedures. In contrast, the applicant stated that CytoCore is a motorized vacuum assisted device that applies vacuum during biopsy and rotates the [fine] needle. Per the applicant, BioPince is a full core firing biopsy device with a 16-to-18-gauge needle, and it is not recommended for head/neck biopsies due to sensitive structures in the head/neck area (*e.g.,* nerves, carotid, vessels, trachea). The applicant further explained that medical society guidelines, including those of the American Thyroid Association (ATA), recommend fine needle aspiration for biopsy of thyroid nodules. In contrast, the applicant stated that CytoCore is designed to obtain core comparable specimens, but using the safe fine needle (25-to-22-gauge), obviating the need for this more invasive procedure for thyroid biopsies.

Based on the evidence submitted, we note the following concerns: The first study is an undated conference poster presentation and it is not clear whether it has been submitted for publication in a peer-reviewed journal. We also have concerns with the generalizability and validity of the findings. The authors did not report their sampling methodology used to obtain the study samples, calling into question the validity of the comparison groups and any inferences made. In addition, the authors did not describe how they addressed important confounding variables that may affect the quality of the biopsy specimen (*e.g.,* ultrasound guided, nature, and location of nodule biopsied), calling into question whether the FNA and core biopsy samples can validly be compared to CytoCore biopsy samples. The study used small sample sizes, a sample of 14 biopsies for the comparison to FNA and a sample of 12 biopsies for the comparison to core biopsies, within one radiology department location, limiting the generalizability of the findings. In addition, it is not clear that the study is limited to thyroid biopsies and the authors did not report any information on patient characteristics (*e.g.,* age or sex) or the nature of the nodule. Furthermore, the study authors reported that there was no significant difference in obtaining a diagnosis between CytoCore and FNA, and CytoCore and core biopsy, which calls into question any claim of the superiority (versus equivalency) of the CytoCore biopsy samples. The study authors reported that the cellular yield of samples obtained with CytoCore were overall superior to FNA biopsy samples, but the metrics to evaluate this and whether this difference was statistically significant were not reported. We note that we are unable to determine the validity of this finding. We also note that, as presented in the poster, the study authors presented two different rates of diagnosis when using CytoCore with no explanation. Specifically, the study authors stated that CytoCore was able to obtain a successful diagnosis in 78 percent of biopsies when compared to FNA and in 99 percent of biopsies when compared to core biopsy. Additionally, the purpose of the study did not include an evaluation of whether CytoCore reduced trauma or increased cellular harvest, but rather sought to evaluate the consistency and diagnostic quality of cellular material obtained with CytoCore using a 22-to-25-gauge fine needle compared to traditional core biopsy. The study authors did not present metrics that might be used to evaluate the amount of trauma as a result of the biopsy procedures (*e.g.,* bleeding or bruising after the biopsy procedures). We note that we are unable to determine the validity of this finding (*i.e.,* using CytoCore compared to core biopsy reduces tissue damage).

The second document submitted with the application as evidence of substantial clinical improvement is an article that is undated and does not list the authors or location of the study. The applicant did not provide any further details regarding the status of the article. The study authors did not use a direct comparison group; rather, they compared their study results to those found in published literature. The paper did not describe the approach used to select the articles used to compare the performance of CytoCore and there is no indication that a systematic literature review was conducted. We note that we are not able to determine if the literature reported rates included in the study are representative of FNA thyroid biopsy results. Similarly, beyond selecting articles that reported US–FNA thyroid biopsies, the paper did not describe whether the study authors assessed the quality of the study designs in the selected literature. We note the paper did not control for confounding factors the study authors stated may impact the adequacy of a biopsy sample, including the skill and knowledge of the person performing the biopsy, the preparation of the specimens, and the nature of the nodule (*e.g.,* size, composition, vascularity). Similarly, we note the study authors did not account for other important potential confounders including the skill and knowledge of the

pathologist and having a cytotechnologist present to perform ROSE on the specimens during the biopsy.

We further note that none of the evidence submitted by the applicant provides conclusive evidence that the use of CytoCore reduces tissue trauma and/or bleeding, increases cellular yield, reduces the number of passes required or clinical invasiveness, or reduces the number of nondiagnostic biopsy results or follow-up. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether CytoCore demonstrates substantial clinical improvement over existing technologies.

Finally, we are concerned that CytoCore may not demonstrate that it substantially improves the diagnosis or treatment of an illness when compared to the benefits of other available treatments. CytoCore was determined to be substantially equivalent to a legally marketed device, the TAO Aspirator and Plastic Finger, which received 510(k) clearance on December 9, 1997. The FDA 510(k) summary for CytoCore indicated that the devices share similar technological characteristics. In fact, the FDA 510(k) summary indicated that CytoCore differs only in that a battery powers a motor that rotates the needle, while the TAO Aspirator is moved manually in an in-and-out motion. In addition, while the applicant distinguishes CytoCore from a comparator device, BioPince, it is our understanding that BioPince is a large gauge full core firing biopsy device that is not recommended for use in the head/neck, the anatomic region for which CytoCore has primary use, according to the application. Therefore it remains unclear how such a comparison with BioPince supports the argument of substantial clinical improvement.

We are inviting public comments on whether CytoCore meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that CytoCore would be reported with HCPCS codes in Table 32.

TABLE 32: HCPCS CODES REPORTED WITH CYTOCORE

HCPCS Code	Long Descriptor	SI	APC
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	T	5071
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion (List separately in addition to code for primary procedure)	**	**
60100	Biopsy thyroid, percutaneous core needle	T	5071

** Denotes a HCPCS code that was not evaluated for the cost criterion because the HCPCS code was not included in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060)..

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5071, which had a CY 2022 payment rate of $635.54 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 10005 had a device offset amount of $0.89 at the time the application was received.[56] According to the applicant, the cost of the CytoCore is $175.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $175.00 for CytoCore is 27.54 percent of the applicable APC payment amount for the service related to the category of devices of $635.54 (($175.00/$635.54) × 100 = 27.54 percent). Therefore, we believe CytoCore meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $175.00 for CytoCore is 19,662.92 percent of the cost of the device-related portion of the APC payment amount for the related service of $0.89 (($175.00/$0.89) × 100 = 19,662.92 percent).

[56] We note that the applicant selected a value of $32.16 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 10005 in APC 5071 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060). We selected the value of $0.89, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of $0.89 would result in CytoCore meeting the cost significance requirement.

Therefore, we believe that CytoCore meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $175.00 for CytoCore and the portion of the APC payment amount for the device of $0.89 is 27.40 percent of the APC payment amount for the related service of $635.54 or ((($175.00 − $0.89)/$635.54) × 100 = 27.40 percent). Therefore, we believe that CytoCore meets the third cost significance requirement.

We are inviting public comment on whether CytoCore meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(c) EchoTip®

Cook Medical submitted an application for a new device category for transitional pass-through payment status for the EchoTip® Insight Portosystemic Pressure Gradient Measurement System® (EchoTip®) for CY 2024. According to the applicant, EchoTip® is used in the diagnosis and management of patient populations with chronic liver diseases (CLDs), and especially with non-alcoholic fatty liver Disease (NAFLD). The applicant stated that EchoTip® directly measures pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. The applicant provided that a physician measures the portosystemic pressure gradient via endoscopic ultrasound guidance, a curvilinear array echoendoscope is advanced to the stomach, and the portal and hepatic veins are visualized under ultrasound guidance. A 25-gauge needle (which is prepared prior to the procedure by attaching it to connection tubing and a disposable transducer) is advanced through the echoendoscope which then punctures the hepatic vein through the liver parenchyma, and a pressure measurement is obtained. Per the applicant, a total of three measurements are obtained, after which the needle is retracted in the scope and the echoendoscope is repositioned for portal vein access. The needle is then advanced to the portal vein where another set of three pressure measurements is obtained. The portosystemic pressure gradient is calculated by determining the difference between the two averaged measurements.

According to the applicant, EchoTip® is a single-use, disposable device comprised of the EchoTip® Insight Needle, a connecting tube, and a Compass CT transducer. EchoTip® is supplied with a 10 ml syringe. Once assembled, EchoTip® is used with an ultrasound endoscope and directly measures pressures in the hepatic and portal venous vasculatures. The EchoTip® Insight Needle is stainless steel, has a handle and protective outer sheath, and attaches to the accessory channel of the endoscope. The polyethylene connecting tube consists of a 90 cm tube, a female luer fitting, a male luer fitting, and a stopcock. The connecting tube is used to attach the transducer to the needle handle. The stopcock is used to aid priming of the assembled components. The Compass CT transducer is a self-calibrating disposable pressure transducer with integrated digital display. EchoTip® is intended for direct measurement and monitoring of physiological pressure, including during the infusion of fluids and therapeutic and diagnostic agents.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on November 20, 2019, FDA granted De Novo classification for EchoTip® as a device to directly measure pressures in the hepatic and portal venous vasculatures and is used in conjunction with an ultrasound endoscope. We received the application for a new device category for transitional pass-through payment status for the EchoTip® on June 29, 2022, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether the EchoTip® meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), the applicant stated that EchoTip® is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied in or on a wound or other skin lesion. According to the applicant, the hepatic vein and portal vein are punctured through the liver parenchyma to obtain pressure measurements.

We are inviting public comment on whether EchoTip® meets the integral part of the service criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that EchoTip® meets the device eligibility requirements because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We are inviting public comment on whether EchoTip® meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described EchoTip® as the only device authorized by the FDA with an indication to directly access and measure pressure in the hepatic and portal venous vasculatures in conjunction with an ultrasound endoscope. Per the applicant, FDA established there is no recognized predicate product, or other similar approved device with a similar mechanism of action. Per the applicant, no previous device categories for pass-through payment have encompassed EchoTip® and there are no similar device categories. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to EchoTip®.

We are inviting public comment on whether EchoTip®meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant claimed that EchoTip® represents a substantial clinical improvement over

existing technologies in the diagnosis and management of chronic liver disease because: (1) Endoscopic ultra-sound-guided direct portal-systemic pressure gradient measurement (EUS–PPG)-guided measurement is clinically safer and more accurate than the current standard transjugular endovascular indirect measurement, referred to as the hepatic venous pressure gradient (HVPG); (2) EUS–PPG is technically feasible and superior to HVPG; (3) EUS–PPG has benefits in non-cirrhotic patients; and (4) EUS–PPG has utility in the evaluation of ESRD patients and kidney transplant candidacy. The applicant provided four articles specifically for the purpose of addressing the substantial clinical improvement criterion claims. The applicant also included one background article that discussed social determinants of health and disparities in liver disease.[57]

In support of the first claim, the applicant submitted an article on a prospective, single-armed, single-academic center study.[58] Patients with suspected liver disease or cirrhosis were enrolled prospectively from 2020 to 2021. EUS–PPG was measured by calculating the difference between the mean portal pressure and the mean hepatic vein pressure. PH was defined as PPG >5 mm Hg and clinically significant PH as PPG <10 mm Hg. The primary outcomes were procedural technical success rate and correlation of EUS–PPG with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling and the correlation of EUS–PPG with patients' imaging, clinical, and laboratory findings. The secondary outcome was occurrence of procedural adverse events. EUS–PPG measurement was successful in 23 patients, leading to a technical success rate of 96 percent. The authors reported that there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P = .559). According to the authors, this did not change after excluding three patients without established chronic liver disease from the analysis. The authors reported that one patient experienced a mild adverse event with postprocedural abdominal pain resulting in an emergency department visit. The authors also reported that five patients (28 percent) received oral acetaminophen in the post anesthesia care unit for mild abdominal pain after the procedure, which resolved in all cases before discharge without the need for further pharmacotherapy.

In support of its second claim, the applicant submitted a single-center retrospective study on patients with various CLDs undergoing EUS–PPG and EUS-guided liver biopsy (EUS–bx) to assess correlation with histological hepatic fibrosis stage and various clinical, laboratory, endoscopic and imaging variables indicative of advanced liver disease.[59] Cases with EUS–PPG were identified at the University of California Irvine, a tertiary endoscopy center, between January 2014 and March 2020. Three different ways of evaluating the EUS–PPG outcomes were assessed: (1) success rate of the EUS–PPG measurement; (2) performance; and (3) safety profile. The primary outcome evaluated was the association between EUS–PPG and the presence of histologic liver fibrosis, stage ≥3. EUS–PPG procedures were successfully completed in all 64 cases. On multivariate analysis, EUS–PPG ≥5 mmHg was significantly associated with fibrosis stage ≥3 on EUG-liver biopsy (LR 27.0, 95% CI = 1.653 – 360.597, p = 0.004), independent from C-cirrhosis, clinical portal hypertension, thrombocytopenia, splenomegaly, aspartate aminotransferase to platelet ration index score >2, and fibrosis-4 score >3.25. There were six complications in total, including abdominal pain (n = 3) and sore throat (n = 3). The authors reported that there were no subjects who had post-EUS–PPG emergency room (ER) visits or hospital admissions.

In support of its third claim, the applicant submitted a review of endoscopic ultrasound guided interventions. The article[60] discussed the diagnosis and treatment of portal hypertension and treatment of gastric varices (GV) and compared liver biopsy, HVPG, and EUS–PPG. With respect to the utility of HVPG, the authors explained that in the absence of fibrosis/nodules (*i.e.,* cirrhosis) the pressure equalizes throughout the interconnected sinusoidal network, and results in minimal gradient (*i.e.,* normal; up to 4 mmHg). Thus, according to the authors, HVPG does not provide useful information regarding prehepatic or presinusoidal portal hypertension (PH) (*i.e.,* non-cirrhotic causes of PH). In comparison, EUS-guided portal pressure gradient (PPG) measurements employ a direct sampling technique. Thus, the study authors found direct measurement of the portal vein pressure could be considered the gold standard because it is not an estimate of sinusoidal pressure as is HVPG. The difference in the mean measurement of these pressures is termed the PPG which is analogous to the HVPG, with the caveat that direct portal vein measurement also allows for the assessment of prehepatic/presinusoidal PH; a limitation of the transjugular approach. The study authors cited a study by Huang et al.[61] that used a porcine animal model with a novel EUS-guided system which included a manometer attached to a 25-gauge fine needle aspiration (FNA) needle for directly measuring pressures in the hepatic and portal veins. The purpose of this animal study was to assess clinical feasibility and assess correlation with the standard of care: HVPG measurement through transjugular approach. The study authors further cited a pilot study involving 28 patients between the age of 18–75 years with a history of liver disease or suspected cirrhosis that underwent EUS–PPG measurements using the technique and equipment in the animal study. The portal vein and hepatic vein were targeted via a transgastric-transduodenal approach (inferior vena cava (IVC) was substituted for hepatic vein when not technically feasible). The technical success rate of EUS–PPG measurement was 100 percent without any adverse events. The study authors concluded that EUS–PPG measurement was a safe and feasible alternative to HVPG measurement.

In support of its fourth claim, the applicant submitted a letter in which the author described a retrospective, single-center study to determine feasibility, safety, and utility of EUS–PPG using EUS-liver biopsy as comparison in patients with end stage renal disease (ESRD) and suspected portal hypertension.[62] According to the

[57] Kardashian, A., Wilder, J., Terrault, N. Price, J. (2021). Addressing Social Determinants of Liver Disease During the COVID–19 Pandemic and Beyond: A Call to Action. *Hepatology* 73 (2): 811–820.

[58] Hajifathalian, K., Westerveld, D., Kaplan, A. et. al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. Gastrointestinal Endoscopy 95(4): 703–710.

[59] Choi, A., Chang, K., Samaransena, J. et. al. (2022). Endoscopic Ultrasound-Guided Porto-systemic Pressure Gradient Measurement Correlates with Histological Hepatic Fibrosis. Digestive Diseases and Sciences. *https://doi.org/10.1007/s10620-022-07418-7.*

[60] Rudnick, S., Conway, J., Russo, M. (2021). Current state of endohepatology: Diagnosis and treatment of portal hypertension and its complications with endoscopic ultrasound. World Journal of Hepatology 13(8): 887–895.

[61] Huang JY, Samarasena JB, Tsujino T, Chang KJ. EUS-guided portal pressure gradient measurement with a novel 25-gauge needle device versus standard transjugular approach: a comparison animal study. Gastrointest Endosc 2016; 84: 358–362 [PMID: 26945557 DOI: 10.1016/j.gie.2016.02.032].

[62] Rubin, R., Mehta, M., Rossi, A., Joeslon, D., Shrestha, R. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient

letter author, the purpose of the study was to investigate the use of EUS–PPG to assess pressure and the recommendation to decide between kidney transplant (KT) or combined liver KT. According to the letter author, the study suggested that new endoscopic and EUS findings were discovered with successful/reproducible EUS–PPG in 10 out of 11 (91 percent) subjects. The author stated there were no significant adverse events such as bleeding related to venous punctures, transfusions, or EUS–PPG-related hospitalizations. The author referenced conclusions from the study citing the need for further studies correlating EUS–PPG with wedged hepatic vein pressure gradient (WHVPG), assess patient experience, and analyze cost/benefit of one-stop versus piecemeal procedures. It is also noted in the letter that WHVPG may not always be feasible in ESRD patients due to catheter-related suprapubic thromboses. We note that this source did not include the original retrospective study, only a letter referencing it and highlighting its potential value to further research.

Based on the evidence submitted with the application, we note the following concerns: a lack of direct comparison of EUS–PPG with HVPG and non-invasive methods, a lack of consistent correlation with liver biopsy, the reliance on non-peer reviewed studies, and small sample sizes.

In the first two claims, the applicant asserted EUS–PPG is clinically safer and more accurate than HVPG and technically superior to HVPG. However, the applicant did not directly compare EUS–PPG and HVPG. The Hajifathalian et. al. study,[63] which supported the first claim, stated EUS–PPG offers an alternative and potentially superior methodology to measure PPG regardless of liver disease etiology, without showing evidence of a direct comparison between EUS–PPG and HVPG. The Choi study,[64] in support of the second claim, directly compared EUS–PPG with EUS-liver biopsy, but it did not compare EUS–PPG with HVPG. The authors cited the lack of direct comparison between EUS–PPG and HVPG as a limitation in the study. Further these two studies had small sample sizes and were conducted at a single site; the Hajifathalian et. al. study included 24 patients while the Choi study included 64 patients.

In addition, we note that the Hajifathalian et. al. study results did not achieve correlation with fibrosis stage obtained from concurrent EUS-guided liver biopsy sampling. According to the authors, there was no statistically significant correlation between the fibrosis stage on histology and measured PPG (P= .559). We are concerned that the lack of correlation would not support the claim that EUS-guided PPG measurement is more accurate than the current method using an indirect measurement with the use of HVPG.

In support of its fourth claim, we note the applicant relied on a letter to the editor that provides a study description rather than submitting the study directly as evidence for its claim.[65] In the enclosed letter, the author also noted that future studies are needed to correlate EUS–PPG with WHVPG. Lastly, the article the applicant provided in support of social determinants of health and disparities did not directly discuss the device. Additional supporting evidence, preferably published peer-reviewed clinical trials that show improved clinical outcomes would help with our assessment of whether EchoTip® demonstrates substantial clinical improvement over existing technologies.

We are inviting public comment on whether EchoTip® meets the substantial clinical improvement criterion at § 419.66(c)(2)(i)

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that EchoTip® would be reported with HCPCS codes listed in Table 33.

TABLE 33: HCPCS CODES REPORTED WITH ECHOTIP®

HCPCS Code	Long Descriptor	SI	APC
43237	Esophagogastroduodenoscopy, flexible, transoral; with endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures	J1	5302
43238	Esophagogastroduodenoscopy, flexible, transoral; with transendoscopic ultrasound-guided intramural or transmural fine needle aspiration biopsy(s), (includes endoscopic ultrasound examination limited to the esophagus, stomach or duodenum, and adjacent structures)	J1	5302

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the

measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. Transplant International 2021 (34): 2903–2904.

[63] Hajifathalian, K., Westerveld, D., Kaplan, A. et. al. (2022). Simultaneous EUS-guided portosystemic pressure measurement and liver biopsy sampling correlate with clinically meaningful outcomes. Gastrointestinal Endoscopy 95(4): 703–710.

[64] Choi, A., Chang, K., Samaransena, J. et. al. (2022). Endoscopic Ultrasound-Guided Porto-systemic Pressure Gradient Measurement Correlates with Histological Hepatic Fibrosis. Digestive Diseases and Sciences. P.7. *https://doi.org/10.1007/s10620-022-07418-7.*

[65] Rubin, R., Mehta, M., Rossi, A., Joeslon, D., Shrestha, R.. (2021). Letter to the Editor: Endoscopic ultrasound guided portal-systemic pressure gradient measurement to determine candidacy for kidney transplant alone versus combined liver kidney transplant in patients with advanced fibrosis or cirrhosis. Transplant International 2021 (34): 2903–2904.

nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5302, which had a CY 2022 payment rate of $1,658.81 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 43238 had a device offset amount of $19.08 at the time the application was received.[66] According to the applicant, the cost of the EchoTip® is $1,965.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $1,965.00 for EchoTip® is 118.46 percent of the applicable APC payment amount for the service related to the category of devices of $1,658.81 (($1,965.00/$1,658.81) × 100 = 118.46 percent). Therefore, we believe EchoTip® meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,965.00 for EchoTip® is 10,298.74 percent of the cost of the device-related portion of the APC payment amount for the related service of $19.08 (($1,965.00/$19.08) × 100 = 10,298.74. Therefore, we believe that EchoTip® meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,965.00 for EchoTip® and the portion of the APC payment amount for the device of $19.08 is 117.31 percent of the APC payment amount for the related service of $1,658.81 ((($1,965.00 − $19.08)/$1,658.81) × 100 = 117.31 percent). Therefore, we believe that EchoTip® meets the third cost significance requirement.

We are inviting public comment on whether the EchoTip® meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

(d) FLEX Vessel Prep ™ System

Venture Med Group, Inc. submitted an application for a new device category for transitional pass-through payment status for FLEX Vessel Prep ™ System (FLEX VP ™) for CY 2024. Per the applicant, FLEX VP ™ is an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with End-Stage Renal Disease (ESRD) on hemodialysis. According to the applicant, FLEX VP ™ is used with percutaneous transluminal angioplasty (PTA) catheters and for the treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. The applicant asserted that FLEX VP ™ consists of three integrated components: (1) control handle, which includes the flush and guidewire ports and sheath and treatment element actuators; (2) catheter shaft; and (3) treatment element, which includes three proximally mounted micro-surgical blades on protective skids. The struts are radially opposed, and the proximal portion of each strut includes a micro-surgical blade. A radiopaque marker is located distally to assist in the positioning of the catheter.

According to the applicant, when deployed, FLEX VP ™'s struts independently engage with neointimal hyperplastic stenoses occluding an arteriovenous fistula or graft used for hemodialysis. As the device is pulled back through the lesion, the blades create three continuous, parallel micro-incisions, approximately 250 microns in depth, along the lesion's entire length. The applicant provided that this is a non-balloon-based device where the struts exert a consistent force of approximately one atmosphere on the vessel wall. Per the applicant, additional micro-incisions may be created by using several passes of the device. According to the applicant, the device breaks the lesion surface to facilitate the effectiveness of a percutaneous transluminal balloon angioplasty, which immediately follows use of the device in restoring patency to the vascular access.

The applicant asserted that the micro-incisions improve acute luminal gain and vessel compliance by releasing circumferential tension in the lesion. The applicant asserted that this preparation can help reduce vessel trauma and complications (including severe dissection and need for a bail-out stent) and the need for high pressure balloons (which risk barotrauma). Per the applicant, the interventionalist advances FLEX VP ™ past the lesion, then unsheathes and expands the treatment element and slowly draws the catheter back, allowing each micro-surgical blade to simultaneously and independently engage with the lesion. This step produces three continuous, parallel micro-incisions along the lesion's length. According to the applicant, this process may be repeated several times; once the lesion is crossed on the first pass, the treatment element is re-sheathed, advanced again through the lesion, and rotated approximately 30 to 90 degrees. The treatment element is then re-deployed and the process is repeated.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), on September 11, 2020, the applicant received 510(k) clearance from FDA for FLEX VP ™ for use with PTA catheters to facilitate dilation of stenoses in the femoral and popliteal arteries and treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for treatment of in-stent restenosis of balloon expandable and self-expanding stents in the peripheral vasculature. We received the application for a new device category for transitional pass-through payment status for FLEX VP ™ on February 28, 2023, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comment on whether FLEX VP ™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criterion at § 419.66(b)(3), according to the applicant, FLEX VP ™ is integral to the service provided, is used for one patient only, comes in contact with human skin, and is applied through an incision (for hemodialysis patients, the incision is in the wrist or arm area). FLEX VP ™

[66] We note that the applicant selected a value of $156.43 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 43238 in APC 5302 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060). We selected the value of $19.08, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of $19.08 would result in EchoTip® meeting the cost significance requirement.

is inserted through the incision over a guidewire until distal to the lesion to be treated and prior to the angioplasty procedure.

We are inviting public comment on whether FLEX VP ™ meets the integral part of the service criterion at § 419.66(b)(3).

With respect to the exclusion criterion at § 419.66(b)(4), the applicant claimed that FLEX VP ™ meets the device eligibility requirements of § 419.66(b)(4) because it is not equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered, and it is not a supply or material furnished incident to a service.

We are inviting public comment on whether FLEX VP™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. The applicant described FLEX VP™ as an endovascular, over-the-wire, retractable, sheathed catheter with a three-strut treatment element at the distal tip used to help resolve stenoses occluding vascular access in patients with ESRD on hemodialysis. Per the applicant, no previous device categories for pass-through payment have encompassed FLEX VP™ and there are no similar device categories. Upon review, it does not appear that there are any existing pass-through payment categories that might apply to FLEX VP™.

We are inviting public comment on whether FLEX VP™ meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant stated that FLEX VP™ represents a substantial clinical improvement over existing technologies by: (1) improving clinical outcomes for the hemodialysis patient population with dysfunctional arteriovenous (AV) access; and (2) reducing the rate of device-related complications. The applicant cited two studies describing the findings of a single clinical trial specifically for the purpose of addressing the substantial clinical improvement criterion.

The first study presented findings 6 months after patients were treated with FLEX VP™ followed by balloon angioplasty (Aruny, et al.),[67] and the second study presented findings at 12 months post-treatment with FLEX VP™ followed by balloon angioplasty (author not identified in the manuscript for the 12-month follow up).[68] Both studies focused on results from methods used to show the durability of the treatments of blocked vascular accesses with FLEX VP™. The trial was a prospective, observational controlled clinical trial. A total of 148 lesions or blockages were treated with FLEX VP™ prior to a PTA in 114 subjects (the population was 53.5 percent female; 65.8 percent Black or African American (B/AA)), treated at eight clinical sites. All subjects were hemodialysis patients with vascular blockages. Of the 114 subjects, 104 patients had prior treatments to correct stenoses before enrolling in the trial. A primary endpoint was anatomic success, defined as angiographic confirmation of <30 percent residual stenosis post-procedure without adverse event. Additional assessments included dialysis circuit primary patency or vascular openness, clinical success and procedural success. The trial also measured the target lesion primary patency (TLPP) and freedom from target lesion restenosis (FFTLR) to determine if there is a decreased rate of subsequent therapeutic interventions. The two studies of the single clinical trial also examined the rate of device-related complications. No serious adverse events were reported initially (Aruny et al.), or in the 12-month follow-up (author not identified in the manuscript for the 12-month follow-up). The studies looked at differences in outcomes based on race and sex and found no significant differences. Per the applicant, the results suggest that FLEX VP™ followed by angioplasty can substantially reduce the number and burden of maintenance procedures for hemodialysis patients with arteriovenous fistula (AVF), arteriovenous graft (AVG), and AV disfunctions that cause cephalic arch stenoses.

In support of its first claim, that FLEX VP™ improves clinical outcomes for the hemodialysis patient population with dysfunctional AV access, the applicant asserted that FLEX VP™ decreased both the rates of therapeutic interventions and subsequent therapeutic interventions. The applicant provided the following evidence from the clinical trial and two studies. FLEX VP™ treatment prior to angioplasty benefits hemodialysis patients by improving the level of openness of blocked (or stenosed) arteriovenous access; a recurring issue that occurs because of the fistulas created to facilitate hemodialysis. The use of FLEX VP™ also allows the site with prior blockage (also known as lesions) to stay opened for a longer period of time, reducing the frequency of future angioplasty procedures. The applicant discussed how the initial study (Aruny et al.), found that patients treated with FLEX VP™ prior to PTA (FLEX+PTA) had 6 months TLPP of 63.7 percent openness, versus the 15.6 percent to 50.5 percent rates of vascular openness after PTA alone observed in other publications. This study also presented results for FFTLR, a calculation to determine an average number of days of durability of the percentage of the patency or lesion openness reported; for the overall hemodialysis population studied it was 206.7 days. The applicant also described results for patients with only AVFs or AVGs. For FLEX+PTA in AVF patients, TLPP was 70.6 percent and FFTLR was 219.7 days. For FLEX+PTA in AVG patients, TLPP was 46.6 percent and FFTLR was 173.9 days. Confirmation of reliability of the findings was shown by dialysis access circuit primary patency: 54.3 percent (AVF 54.1 percent; AVG 47.4 percent). According to the applicant, results of dialysis access circuit primary patency derived from the literature with only angioplasty performed ranged from 0 percent to 48 percent. The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow up) supporting the durability of the FLEX+PTA. Per the applicant, results generally accord with Aruny et al.'s 6-month results and exceed PTA-only

[67] Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

[68] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

results from the literature. Overall, TLPP was 45.7 percent (versus 62.2 percent at 6 months) and FFTLR was 250.9 days (versus literature (PTA only), 131.4 days). Per the applicant, this result suggests that compared to the durability of PTA only, FTA+PTA would result in a lower frequency of treatments to remove stenosis in overall hemodialysis patients. For AVFs, TLPP was 47.4 percent (versus 67.5 percent at 6 months); FFTLR was 258.5 days (versus literature, 156.9 days). For AVGs, TLPP was 43.8 percent (versus 52.4 percent at 6 months); FFTLR was 239.4 days (versus literature, 76.6 days). Overall, 12 months circuit primary patency was 36.5 percent (versus 54.3 percent at 6 months).[69]

In further support of the applicant's first claim, the applicant presented results from the clinical trial comparing B/AA patients to non-B/AA patients. In support of FLEX VP™ prior to PTA improving clinical outcomes for B/AA hemodialysis patient population with dysfunctional AV access, the applicant discussed the initial Aruny et al. study, in which B/AA patients had better results with FLEX VP™ intervention than did non-B/AA patients. The B/AA cohort (65.8 percent of sample) had TLPP of 63.76 percent versus 58.8 percent for the non-B/AA cohort after treatment with FLEX+PTA. FFTLR was 207.8 days for B/AA versus 192.2 days for non-B/AA. For B/AA patients with cephalic arch lesions, TLPP was 78.6 percent versus 58.3 percent for non-B/AA. The applicant asserted that these results were achieved despite pre-existing disparities in patient's experience with AV access care. B/AA patients had more years since they started hemodialysis ($p<0.01$), suggesting a possibility of increased severity or complexity of lesions in the B/AA patients.[70] The applicant also presented results 12 months post-treatment.[71] In terms of B/AA patient outcomes comparable to the overall sample, the B/AA cohort (65.8 percent of sample) had TLPP of 45.9 percent versus 45.7 percent overall patients and FFTLR was 257.8 days for B/AA versus 250.9 days overall patients. In B/AA patients with cephalic arch lesions, TLPP was 71.8 percent versus 59.7 percent overall patients.

Furthermore, in support of the applicant's first claim, the applicant provided the following evidence from the clinical trial. In support of FLEX VP™ improving clinical outcomes for a female hemodialysis patient population with dysfunctional AV access, the applicant stated that in the initial Aruny et al. study, females differed from males significantly in their pre-existing experiences with AV care. Female patients had more years since they started hemodialysis ($p<0.01$) and since AV access creation ($p<0.01$) and more prior AV access interventions ($p<0.05$); according to the applicant, this potentially suggests that female patients are more prone to complexity of lesions or recurrence of stenosis. However, no statistically significant differences in results of TLPP and FFTLR measures at 6 months post treatment were observed between females and males treated with FLX VP™ followed by PTA. Therefore, females receiving a FLEX VP™ intervention prior to PTA achieved results comparable to males, notwithstanding pre-existing disparities.[72]

In further support of the applicant's first claim, the applicant explained that cephalic arch (CA) stenoses are notoriously difficult to treat effectively and have some of the worst results in dialysis access results and recurrence of the lesions in a short amount of time. The applicant explained that complications are also high. In this sample, the target stenosis was in the CA in 25/114 patients (21.9 percent). TLPP following FLEX+PTA at 6 months (Aruny et al.) was 70.6 percent overall patients, and 76.8 percent in the B/AA cohort. According to the applicant comparable figures in the literature ranged from 0 percent to 51.6 percent. Access dialysis circuit primary patency gathered from the literature for PTA only was 66.4 percent for CA cases.[73] The applicant also presented results 12-month post-treatment (author not identified in the manuscript for the 12-month follow up). TLPP for these patients following FLEX+PTA at 12 months was 59.7 percent for overall patients and 71.8 percent in the B/AA cohort. According to the applicant, comparable figures in the clinical literature ranged from 0 percent to 33.9 percent and access dialysis circuit primary patency was 55.3 percent for CA cases.[74]

In support of the applicant's second claim, the applicant asserted that no serious adverse events were reported from the initial study (Aruny et al.). Five procedural complications and one dissection related to the FLEX VP™ device were recorded. Three dissections were associated with PTA.[75] The applicant also presented results 12 months post-treatment (author not identified in the manuscript for the 12-month follow-up), noting that no serious adverse events were reported during 12-month follow-up.

According to the applicant, these findings confirm the safety record for FLEX VP™, which is better when compared to the Journal of Vascular and Interventional Radiology (JVIR) Quality Improvement Guidelines thresholds for AVF and AVG. According to the applicant, in the literature, up to 15% cephalic arch lesions result in vessel rupture and about 12% of PTAs in B/AA patients are reported to result in major complications.[76]

Ultimately, the applicant concluded that FLEX VP™ is safe and effective, notably in patients with AVGs and those with CA stenoses, and furthermore, despite observed differences in time since hemodialysis onset, clinical success was similar across sex and race, suggesting an opportunity to enhance health equity.[77] The applicant also added that FLEX VP™, when used with PTA, provides sustained clinical improvement over existing technologies by increasing the patency and time to reintervention of PTA procedures in AVFs and AVGs at 12 months (author not identified in the manuscript for the 12-month follow-up), while reducing the potential for serious complications, such as perforations and vessel rupture. Favorable results at 6 months for the B/AA cohort reported in Aruny et al.'s article were sustained in the 12 month

[69] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

[70] Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

[71] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

[72] Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

[73] Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

[74] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

[75] Aruny et al., Real-World Results on a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

[76] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

[77] Aruny et al., Real-World Results of a Novel Vessel Preparation Device Prior to Balloon Angioplasty for Arteriovenous Access Repair in Diverse Populations on Dialysis, under review, JVA, Feb. 2023.

results. Further, according to the applicant, the use of FLEX VP™ offers the prospect of improved treatment of unresponsive or difficult to treat stenosis in the cephalic arch.[78]

Based on the evidence submitted in the application, we note the following concerns: The applicant presented two studies (Aruny et al. [a 6-month follow up], and an unpublished manuscript which did not identify an author [12-month follow up] submitted with the application) that are based on a single clinical trial of 114 patients followed for 12 months. Per the applicant, the results from the 6-months follow up are not yet published, and the results from 12-months post-treatment are also unpublished and only available at the FLEX VP™ registry. Therefore, we note that the evidence presented on benefits to patients in hemodialysis is not peer-reviewed and this may reduce the strength of the evidence presented and the opinion of peers on study quality. In order to demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. We also note that, due to the clinical trial design, there is insufficient data on the impact of angioplasty with the drug-coated balloon option. The drug in these balloons may play a role in the improvement of patency or openness durability and additional studies to strengthen the initial observations presented by the applicant would be helpful.

Lastly, we note the applicant did not show a clear crosswalk of findings or data in terms of device-related complications (including dissection and embolectomy) observed in the trial and compared to those referenced in literature. For example, procedural complications and dissection were mentioned in the FLEX VP™ group while rupture and major complications were mentioned in the literature. The clinical trial results presented one dissection attributed to FLEX VP™ after 148 lesions were treated with FLEX VP™ plus PTA. Per the applicant, there are approximately 732,000 interventions per year in the U.S. to maintain lifesaving arteriovenous access and FLEX VP™ could be potentially used in a fraction of those; this increases the concern for frequency of complications and therefore, additional studies may be needed to strengthen the second substantial clinical improvement claim.

We are inviting public comment on whether FLEX VP™ meets the substantial clinical improvement criterion at § 419.66(c)(2)(i).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant provided the following information in support of the cost significance requirements. The applicant stated that FLEX VP™ would be reported with HCPCS codes listed in Table 34.

TABLE 34: HCPCS CODES REPORTED WITH FLEX VP™

HCPCS Code	Long Descriptor	SI	APC
36902	Introduction of catheters, dialysis circuit, with transluminal balloon angioplasty	J1	5192
36903	Introduction of catheters, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	J1	5193
36905	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transluminal balloon angioplasty	J1	5193
36906	Percutaneous transluminal mechanical thrombectomy, dialysis circuit, with transcatheter placement of intravascular stent and all angioplasty	J1	5194

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule with comment period (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. For our calculations, we used APC 5192, which had a CY 2022 payment rate of $5,061.89 at the time the application was received. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). HCPCS code 36902 had a device offset amount of $1,271.04 at the time the application was received.[79] According to the applicant, the cost of FLEX VP ™ is $1,995.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The estimated average reasonable cost of $1,995.00 for FLEX VP ™ is 39.41 percent of the applicable APC payment amount for the

[78] Durability of Arteriovenous Access Repair Involving Vessel Preparation by Longitudinal Micro-Incisions Before Balloon Angioplasty; unpublished manuscript (no author identified).

[79] We note that the applicant selected a value of $1,391.99 for the device offset amount. However, the value selected is inconsistent with the device offset amount related to HCPCS 36902 in APC 5192 found in Addendum P to the CY 2022 OPPS/ASC final rule with comment period, as corrected in the 2022 Correction Notice OPPS Addendum (87 FR 2060). We selected the value of $1,271.04, which we believe is the accurate value. Based on our initial assessment for this proposed rule, using the device offset amount of $1,271.04 would result in FLEX VP ™ meeting the cost significance requirement.

service related to the category of devices of $5,061.89 (($1,995.00/$5,061.89) × 100 = 39.41 percent). Therefore, we believe FLEX VP ™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,995.00 for FLEX VP ™ is 156.96 percent of the cost of the device-related portion of the APC payment amount for the related service of $1,271.04 (($1,995.00/$1,271.04) × 100 = 156.96 percent). Therefore, we believe that FLEX VP ™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,995.00 for FLEX VP ™ and the portion of the APC payment amount for the device of $1,271.04 is 14.30 percent of the APC payment amount for the related service of $5,061.89 ((($1,995.00 − $1,271.04)/$5,061.89) × 100 = 14.30 percent). Therefore, we believe that FLEX VP ™ meets the third cost significance requirement.

We are inviting public comment on whether FLEX VP ™ meets the device pass-through payment criteria discussed in this section, including the cost criterion for device pass-through payment status.

B. Proposed Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4 of this proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3 of this proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria listed below. Historically, the device-intensive designation was at the APC level and applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3 and IV.C.4 of this proposed rule.

b. Use of the Three Criteria To Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed;
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy—which includes the three criteria listed previously—to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Device-Intensive Procedure Policy for CY 2019 and Subsequent Years

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not either of the following:

(a) Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

(b) A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data; instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no

clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically at *outpatientpps@cms.hhs.gov*. Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2024 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2024 OPPS/ASC proposed rule on our website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps*.

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) is reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device that are assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)) will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is ''Implantable/insertable device, not otherwise classified''. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71830), we described a commenter's concern about the potentially inadequate payment rate for APC 5495 (Level 5 Intraocular Procedures) and their recommendation that we use our equitable adjustment authority to limit the potential reduction in the CY 2023 APC payment rate by applying a 10 percent cap on the reduction in relative weights for Low Volume APCs in CY 2023. While we did not accept the commenter's recommendation to limit a Low Volume APC's decline in relative weight to no more than 10 percent, we stated we would continue to monitor the costs and payment rates for procedures assigned to Low Volume APCs to determine if additional changes or refinements to our current policy are needed.

In our review of claims data for CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis), we noticed unusual coding, charge, and cost data in the claims data from CY 2017, CY 2018, CY 2019, and CY 2021. Some claims did not report the correct device code—HCPCS code C1840 (Lens, intraocular (telescopic))—and such claims had substantially lower cost than claims that reported the correct device code. In particular, claims that reported the correct device code had an average device cost of $15,030.04, while claims that did not report the correct device code had an average device cost of $430.72. The vast majority of claims for CPT code 0308T in our 4-year analysis did report the correct device code; however, the limited number of claims that either reported the wrong procedure code or reported the wrong device code had an outsized impact on the APC payment rate because of the very low volume of claims for this APC. Because payment stability for this Low Volume APC relies so critically on accurate reporting of the procedure's associated costs, we believe this APC would benefit from a procedure-to-device edit—a claims processing edit that requires a certain device code to be included on the claim when hospitals report a specific procedure code. The procedures associated with the Level 5 Intraocular APC, which we propose to reassign to a new Level 6 Intraocular APC (APC 5496) in section III.E of this proposed

rule, describe the implantation of a specific device codes:

- CPT code 0308T (Insertion of ocular telescope prosthesis including removal of crystalline lens or intraocular lens prosthesis) describes the implantation of device HCPCS code C1840 (Lens, intraocular (telescopic));
- CPT code 0616T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; without removal of crystalline lens or intraocular lens, without insertion of intraocular lens) describes the implantation of device HCPCS code C1839 (Iris prosthesis);
- CPT code 0617T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with removal of crystalline lens and insertion of intraocular lens) describes the implantation of device HCPCS code C1839 (Iris prosthesis); or
- CPT code 0618T (Insertion of iris prosthesis, including suture fixation and repair or removal of iris, when performed; with secondary intraocular lens placement or intraocular lens exchange) also describes the implantation of device HCPCS code C1839 (Iris prosthesis).

We propose to establish a procedure-to-device edit for the four aforementioned procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures. While some interested parties have previously recommended in past rulemaking that we reestablish all of our previous procedure-to-device edits, we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). We continue to rely on hospitals' accurate reporting and believe our current device edits policy of requiring device-intensive procedures to be subject to an additional device reporting edit has improved our ratesetting for hospital outpatient department procedures without placing an undue burden on hospitals. However, we believe this APC represents a unique situation—the APC (which was the Level 5 Intraocular APC in previous years) has been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than $15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. We believe requiring a procedure-to-device edit for procedures assigned to the APC 5496 (Level 6 Intraocular Procedures), would not be administratively burdensome to hospitals given the low volume of services associated for this APC and will have a meaningful and significant impact on the payment rate for this APC and the stability of the payment rate in the future.

We are soliciting comments on our proposal to modify our device edits policy to require a procedure-to-device edit for procedures assigned to APC 5496 (Level 6 Intraocular Procedures) for CY 2024.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the ''FB'' modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the ''FC'' modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the ''FB'' and ''FC'' modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code ''FD'' (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the ''FD'' value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit.

Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code ''FD'' when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including Chapter 4, Section 61.3.6 of the Medicare Claims Processing Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2024.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or ''transitional pass-through payments'' for certain drugs and biologicals. Throughout the proposed rule, the term ''biological'' is used because this is the term that appears in section 1861(t) of the Act. A ''biological'' as used in the proposed rule includes (but is not necessarily limited to) a ''biological product'' or a ''biologic'' as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. ''Current'' refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain ''new'' drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is ''not insignificant'' in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as ''drugs.'' As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2024 pass-through drugs and biologicals and their designated APCs are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available on the CMS website).[80]

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. These regulations specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological.

Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In the proposed rule, the term ''ASP methodology'' and ''ASP-based'' are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

The pass-through application and review process for drugs and biologicals is described on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html.*

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Our current policy is to accept pass-through applications on a quarterly basis and to begin pass-through payments for approved pass-through drugs and biologicals on a quarterly basis through the next available OPPS quarterly update after the approval of a drug's or biological's pass-through status. However, prior to CY 2017, we expired pass-through status for drugs and biologicals on an annual basis through notice-and-comment rulemaking (74 FR 60480). In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), we finalized a policy change, beginning with pass-through drugs and biologicals approved in CY 2017 and subsequent calendar years, to allow for a quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through drugs, biologicals, and radiopharmaceuticals.

This change eliminated the variability of the pass-through payment eligibility period, which previously varied based on when a particular application was initially received. We adopted this change for pass-through approvals beginning on or after CY 2017, to allow, on a prospective basis, for the maximum pass-through payment period for each pass-through drug without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

[80] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

3. Drugs and Biologicals With Expiring Pass-Through Payment Status in CY 2023

There are 43 drugs and biologicals for which pass-through payment status expires by December 31, 2023, as listed in Table 35. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2020 through December 31, 2023. In accordance with the policy finalized in CY 2017 and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including diagnostic radiopharmaceuticals, contrast agents, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year (which is proposed to be $140 for CY 2024), as discussed further in section V.B.1 of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2 of this proposed rule.

BILLING CODE 4120–01–P

TABLE 35: DRUGS AND BIOLOGICALS FOR WHICH PASS - THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0179	Injection, brolucizumab-dbll, 1 mg	G	9340	04/01/2020	03/31/2023
J0223	Injection, givosiran, 0.5 mg	G	9343	04/01/2020	03/31/2023
J0791	Injection, crizanlizumab-tmca, 1 mg	G	9359	04/01/2020	03/31/2023
J1201	Injection, cetirizine hydrochloride, 1 mg	G	9361	04/01/2020	03/31/2023
J7331	Hyaluronan or derivative, synojoynt, for intra-articular injection, 1 mg	G	9337	04/01/2020	03/31/2023
Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	G	9341	04/01/2020	03/31/2023
Q5115	Injection, rituximab-abbs, biosimilar (truxima), 10 mg	G	9336	04/01/2020	03/31/2023
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo) 0.5 mg	G	9345	04/01/2020	03/31/2023
J0742	Injection, imipenem 4 mg, cilastatin 4 mg and relebactam 2 mg	G	9362	07/01/2020	06/30/2023
J0896	Injection, luspatercept aamt, 0.25 mg	G	9347	07/01/2020	06/30/2023
J1429	Injection, golodirsen, 10 mg	G	9356	07/01/2020	06/30/2023
J1738	Injection, meloxicam, 1 mg	G	9371	07/01/2020	06/30/2023
J3032	Injection, eptinezumab-jjmr, 1 mg	G	9357	07/01/2020	06/30/2023
J3241	Injection, teprotumumab-trbw, 10 mg	G	9355	07/01/2020	06/30/2023
J7204	Injection, factor VIII, antihemophilic factor	G	9354	07/01/2020	06/30/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
	(recombinant), (esperoct), glycopegylated-exei, per iu				
J7402	Mometasone furoate sinus implant, 10 micrograms (Sinuva)	G	9346	07/01/2020	06/30/2023
J9177	Injection, enfortumab vedotin-ejfv, 0.25 mg	G	9364	07/01/2020	06/30/2023
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg	G	9353	07/01/2020	06/30/2023
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	G	9350	07/01/2020	06/30/2023
Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg	G	9348	07/01/2020	06/30/2023
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 10 mg	G	9367	07/01/2020	06/30/2023
A9591	Fluoroestradiol F 18, diagnostic, 1 millicurie	G	9370	10/01/2020	09/30/2023
C9067	Gallium ga-68, dotatoc, diagnostic, 0.01 mCi	G	9323	10/01/2020	09/30/2023
J7351	Injection, bimatoprost, intracameral implant, 1 microgram	G	9351	10/01/2020	09/30/2023
J9144	Injection, daratumumab, 10 mg and hyaluronidase-fihj	G	9378	10/01/2020	09/30/2023
J9227	Injection, isatuximab-irfc, 10 mg	G	9377	10/01/2020	09/30/2023
J9281	Mitomycin pyelocalyceal instillation, 1 mg	G	9374	10/01/2020	09/30/2023
J9317	Injection, sacituzumab govitecan-hziy, 2.5 mg	G	9376	10/01/2020	09/30/2023
J9318	Injection, romidepsin, non-lyophilized, 0.1 mg	G	9428	10/01/2020	09/30/2023
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	G	9382	10/01/2020	09/30/2023
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	G	9349	10/01/2020	09/30/2023
Q5121	Injection, infliximab-axxq, biosimilar, (AVSOLA), 10 mg	G	9381	10/01/2020	09/30/2023
A9592	Copper Cu-64, dotatate, diagnostic, 1 millicurie	G	9383	01/01/2021	12/31/2023

CY 2023 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0699	Injection, cefiderocol, 10 mg	G	9380	01/01/2021	12/31/2023
J1427	Injection, viltolarsen, 10 mg	G	9386	01/01/2021	12/31/2023
J1437	Injection, ferric derisomaltose, 10 mg	G	9388	01/01/2021	12/31/2023
J1554	Injection, immune globulin (Asceniv), 500 mg	G	9392	01/01/2021	12/31/2023
J9037	Injection, belantamab mafodontin-blmf, 0.5 mg	G	9384	01/01/2021	12/31/2023
J9198	Gemcitabine hydrochloride, (Infugem), 100 mg	G	9387	01/01/2021	12/31/2023
J9223	Injection, lurbinectedin, 0.1 mg	G	9389	01/01/2021	12/31/2023
J9316	Injection, pertuzumab, trastuzumab, and hyaluronidase-zzxf, per 10 mg	G	9390	01/01/2021	12/31/2023
J9349	Injection, tafasitamab-cxix, 2 mg	G	9385	01/01/2021	12/31/2023
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9391	01/01/2021	12/31/2023

BILLING CODE 4120–01–C

4. Proposed Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Expiring in CY 2024

We propose to end pass-through payment status in CY 2024 for 25 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2021, and January 1, 2022, are listed in Table 36. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2024, are assigned status indicator ''G'' (Pass-Through Drugs and Biologicals) in Addenda A and B to this proposed rule (which are available on the CMS website).[81] The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status, are assigned status indicator ''G'' only for the duration of their pass-through status.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise

[81] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2024 and subsequent years, we propose to continue to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2024. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, we propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals under the CY 2024 OPPS, and in subsequent years, because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is also proposed to be the same payment rate, which is generally ASP plus 6 percent, is $0. We propose that this policy and the other policies proposed in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPPS. Therefore, we do not believe the policies need to be re-proposed annually and should apply for subsequent years until such time as we propose to change them.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This proposed payment rate would generally be ASP plus 6 percent for CY 2024 and subsequent years, minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological as described in section V.A.6 of this proposed rule. We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on the CMS website during CY 2024 and subsequent years if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2024 or subsequent years, we propose to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we propose to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.b of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.b of this proposed rule). If WAC information also is not available, we propose to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 36 below for the list of drugs and biologicals with pass-through payment status expiring during CY 2024.

BILLING CODE 4120–01–P

TABLE 36: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0224	J0224	Injection, lumasiran, 0.5 mg	G	9407	04/01/2021	03/31/2024
J7212	J7212	Factor viia (antihemophilic factor, recombinant)-jncw (sevenfact), 1 microgram	G	9395	04/01/2021	03/31/2024
Q5122	Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg	G	9406	04/01/2021	03/31/2024
A9593	A9593	Gallium ga-68 psma-11, diagnostic, (ucsf), 1 millicurie	G	9409	07/01/2021	06/30/2024
A9594	A9594	Gallium ga-68 psma-11, diagnostic, (ucla), 1 millicurie	G	9410	07/01/2021	06/30/2024
J0741	J0741	Injection, cabotegravir and rilpivirine, 2mg/3mg	G	9414	07/01/2021	06/30/2024
J1305	J1305	Injection, evinacumab-dgnb, 5mg	G	9416	07/01/2021	06/30/2024
J1426	J1426	Injection, casimersen, 10 mg	G	9412	07/01/2021	06/30/2024
J1448	J1448	Injection, trilaciclib, 1mg	G	9415	07/01/2021	06/30/2024
J9247	J9247	Injection, melphalan flufenamide, 1mg	G	9417	07/01/2021	06/30/2024
J9348	J9348	Injection, naxitamab-gqgk, 1 mg	G	9408	07/01/2021	06/30/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J9353	J9353	Injection, margetuximab-cmkb, 5 mg	G	9418	07/01/2021	06/30/2024
Q2054	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9413	07/01/2021	06/30/2024
Q5123	Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg	G	9411	07/01/2021	06/30/2024
J1823	J1823	Injection, inebilizumab-cdon, 1 mg	G	9394	10/01/2021	09/30/2024
J2406	J2406	Injection, oritavancin (kimyrsa), 10 mg	G	9427	10/01/2021	09/30/2024
J9061	J9061	Injection, amivantamab-vmjw, 10 mg	G	9432	10/01/2021	09/30/2024
J9272	J9272	Injection, dostarlimab-gxly, 100 mg	G	9431	10/01/2021	09/30/2024
J9359	J9359	Injection, loncastuximab tesirine-lpyl, 0.075 mg	G	9205	10/01/2021	09/30/2024
Q2055	Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells,	G	9422	10/01/2021	09/30/2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		including leukapheresis and dose preparation procedures, per therapeutic dose				
A9595	A9595	Piflufolastat f-18, diagnostic, 1 millicurie	G	9430	01/01/2022	12/31/2024
J0219	J0219	Injection, avalglucosidase alfa-ngpt, 2 mg	G	9433	01/01/2022	12/31/2024
J0491	J0491	Injection, anifrolumab-fnia, 1 mg	G	9434	01/01/2022	12/31/2024
J9021	J9021	Injection, asparaginase, recombinant, (rylaze), 0.1 mg	G	9437	01/01/2022	12/31/2024
J9071	J9071	Injection, cyclophosphamide, (auromedics), 5 mg	G	9203	01/01/2022	12/31/2024

BILLING CODE 4120–01–C

5. Proposed Drugs, Biologicals, and Radiopharmaceuticals With Pass-Through Payment Status Continuing Through CY 2024

We propose to continue pass-through payment status in CY 2024 for 42 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2022, and April 1, 2023, are listed in Table 37. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2024, are assigned status indicator ''G'' in Addenda A and B to this proposed rule (which are available on the CMS website).[82]

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2024 and subsequent years, we propose to continue to pay for pass-through drugs and biologicals at a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but is generally ASP plus 6 percent, which is equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2024. We propose that a $0 pass-through payment amount would be paid for pass-through drugs and biologicals that are not policy-packaged as described in section V.B.1.c of this proposed rule under the CY 2024 OPPS and in subsequent years, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including contrast agents, diagnostic radiopharmaceuticals, and stress agents); and drugs and biologicals that function as supplies when used in a surgical procedure), we propose that their pass-through payment amount would be equal to a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but would generally be ASP plus 6 percent for CY 2024, minus a payment offset for any predecessor drug products contributing to the pass-through payment as described in section V.A.6 of this proposed rule). We propose this policy because, if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore,

[82] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

there are associated OPD fee schedule amounts for them.

We propose to continue to update pass-through payment rates on a quarterly basis on our website during CY 2024, and in subsequent years, if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2024 and subsequent years, consistent with our CY 2023 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2024, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which would generally be ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.b of this proposed rule), the equivalent payment provided to pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.b of this proposed rule). If WAC information also is not available, we would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We propose that the other policies proposed in this section would apply in both CY 2024 and subsequent years as they have been our longstanding policies under the OPPS. Therefore, we do not believe the policies need to be re-proposed annually and should apply for subsequent years until such time as we propose to change them.

The drugs and biologicals that we propose would have pass-through payment status expire after December 31, 2024, are shown in Table 37.

BILLING CODE 4120–01–P

TABLE 37: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2024

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
C9092	J3299	Injection, triamcinolone acetonide, suprachoroidal (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
C9093	J2779	Injection, ranibizumab, via sustained release intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
C9091	J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
C9090	J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including	G	9498	07/01/2022	06/30/2025

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
		leukapheresis and dose preparation procedures, per therapeutic dose				
J1302	J1302	Inj, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
J9274	J9274	Inj, tebentafusp-tebn, 1 mcg	G	9446	07/01/2022	06/30/2025
J1306	J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	J2777	Inj, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
A9602	A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025
J1952	J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025
J0225	J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	J1932	Injection, lanreotide, (cipla), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
C9146	C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
C9147	C9147	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
C9148	C9148	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
C9149	C9149	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026

CY 2023 HCPCS Code	CY 2024 HCPCS Code	Long Descriptor	CY 2023 Status Indicator	CY 2023 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	J1954	Injection, leuprolide acetate for depot suspension (lutrate), 7.5 mg	G	9136	04/01/2023	03/31/2026
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026

BILLING CODE 4120–01–C

6. Proposed Provisions for Reducing Transitional Pass-Through Payments for Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals To Offset Costs Packaged Into APC Groups

Under the regulation at 42 CFR 419.2(b)(15), nonpass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged in the OPPS. This category includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and other diagnostic drugs. Also, under the regulation at 42 CFR 419.2(b)(16), nonpass-through drugs and biologicals that function as supplies in a surgical procedure are packaged in the OPPS. This category includes skin substitutes and other surgical-supply drugs and biologicals. Finally, under the regulation at 42 CFR 419.2(b)(4), anesthesia drugs are packaged in the OPPS. As described earlier, section 1833(t)(6)(D)(i) of the Act specifies that the transitional pass-through payment amount for pass-through drugs and biologicals is the difference between the amount paid under section 1842(o) of the Act and the otherwise applicable OPD fee schedule amount. Because a payment offset is necessary in order to provide an appropriate transitional pass-through payment, we deduct from the pass-through payment for policy-packaged drugs, biologicals, and radiopharmaceuticals an amount reflecting the portion of the APC payment associated with predecessor products in order to ensure no duplicate payment is made. This amount reflecting the portion of the APC payment associated with predecessor products is called the payment offset.

The payment offset policy applies to all policy-packaged drugs, biologicals, and radiopharmaceuticals. For a full description of the payment offset policy as applied to policy-packaged drugs, which include diagnostic radiopharmaceuticals, contrast agents, stress agents, and skin substitutes, we refer readers to the discussion in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70430 through 70432). For CY 2024 and subsequent years, as we did in CY 2023, we propose to continue to apply the same policy-packaged offset policy to payment for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes. We propose that these policies would apply in both CY 2024 and subsequent years as they are our longstanding policies under the OPPS, and we do not believe they need to be re-proposed annually. Instead, we believe they should apply for subsequent years until such time as we propose to change them or until such time as the APCs to which a payment offset may be applicable for certain products change. The APCs to which a payment offset may be applicable for pass-through diagnostic radiopharmaceuticals, pass-through contrast agents, pass-through stress agents, and pass-through skin substitutes are identified in Table 38.

TABLE 38: APCs TO WHICH A POLICY-PACKAGED DRUG OR RADIOPHARMACEUTICAL OFFSET MAY BE APPLICABLE IN CY 2023

CY 2023 APC	CY 2023 APC Title
Diagnostic Radiopharmaceutical	
5591	Level 1 Nuclear Medicine and Related Services
5592	Level 2 Nuclear Medicine and Related Services
5593	Level 3 Nuclear Medicine and Related Services
5594	Level 4 Nuclear Medicine and Related Services
Contrast Agent	
5571	Level 1 Imaging with Contrast
5572	Level 2 Imaging with Contrast
5573	Level 3 Imaging with Contrast
Stress Agent	
5722	Level 2 Diagnostic Tests and Related Services
5593	Level 3 Nuclear Medicine and Related Services
Skin Substitute	
5054	Level 4 Skin Procedures
5055	Level 5 Skin Procedures

We propose to continue to post annually on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Annual-Policy-Files.html* a file that contains the APC offset amounts that will be used for that year for purposes of both evaluating cost significance for candidate pass-through payment device categories and drugs and biologicals and establishing any appropriate APC offset amounts. Specifically, the file will continue to provide the amounts and percentages of APC payment associated with packaged implantable devices, policy-packaged drugs, and threshold packaged drugs and biologicals for every OPPS clinical APC.

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals Without Pass-Through Payment Status

1. Proposed Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment in order to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $135 for CY 2023 (87 FR 71960 through 71961).

Following the CY 2007 methodology, for this proposed rule, we use the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2024 and round the resulting dollar amount ($138.44) to the nearest $5 increment, which yielded a figure of $140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the various price

indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations using the CY 2007 OPPS methodology, we propose a packaging threshold for CY 2024 of $140.

b. Packaging of Payment for HCPCS Codes That Describe Certain Drugs, Certain Biologicals, and Certain Therapeutic Radiopharmaceuticals Under the Cost Threshold (''Threshold-Packaged Drugs'')

To determine the proposed CY 2024 packaging status for all nonpass-through drugs and biologicals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2022 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2022 claims processed through June 30, 2022, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2024: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure.

In order to calculate the per day costs for drugs, biologicals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2024, we use the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate based on the ASP methodology, which is generally ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals) for CY 2024, as discussed in more detail in section V.B.2.b of this proposed rule) to calculate the CY 2024 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2022 (data that were used for payment purposes in the physician's office setting, effective April 1, 2023) to determine the proposed rule per day cost.

As is our standard methodology, for CY 2024 we propose to use payment rates based on the ASP data from the fourth quarter of CY 2022 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2024 OPPS/ASC proposed rule. These data also were the basis for drug payments in the physician's office setting, effective April 1, 2023. For items that did not have an ASP-based payment rate, such as some therapeutic radiopharmaceuticals, we used their mean unit cost derived from the CY 2022 hospital claims data to determine their per day cost.

We propose to package items with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy-packaged. Consistent with our past practice, we cross-walked historical OPPS claims data from the CY 2022 HCPCS codes that were reported to the CY 2023 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website) [83] for proposed payment in CY 2024.

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period. We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year. Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs and biologicals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2022, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2023, along with updated hospital claims data from CY 2022. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

Payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of this proposed rule are based on ASP data from the second quarter of CY 2023. These data will be the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2023. These payment rates would then be updated in the January 2024 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2024. For items that do not currently have an ASP-based payment rate, we calculated their mean unit cost from all of the CY 2022 claims data and updated cost report information available for this proposed rule to determine their final per day cost.

Consequently, the packaging status of some HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals in this OPPS/ASC proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for the final rule with comment period. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS (69 FR 65780) in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2024 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2023. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2024 and subsequent years, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs and biologicals that were paid separately in CY 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would continue to receive separate payment in CY 2024.
- HCPCS codes for drugs and biologicals that were packaged in CY 2023 and that are proposed for separate payment in CY 2024, and that then have per day costs equal to or less than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would remain packaged in CY 2024.
- HCPCS codes for drugs and biologicals for which we proposed

[83] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

packaged payment in CY 2024 but that then have per-day costs greater than the CY 2024 final rule drug packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2024 final rule, would receive separate payment in CY 2024.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as ''policy-packaged'' drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));
- Intraoperative items and services (§ 419.2(b)(14));
- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including, but not limited to, diagnostic radiopharmaceuticals, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and
- Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than that at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: ''We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy'' (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

We welcome ongoing dialogue and engagement from interested parties regarding suggestions for payment changes for consideration in future rulemaking.

d. Packaging Determination for HCPCS Codes That Describe the Same Drug or Biological But Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2024.

For CY 2024, in order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2022 claims data and our pricing information, which is based on the ASP methodology, which is generally ASP plus 6 percent, across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2022 claims data to make the proposed packaging determinations for these drugs: HCPCS code C9257 (Injection, bevacizumab, 0.25 mg); HCPCS code J1840 (Injection, kanamycin sulfate, up to 500 mg); HCPCS code J1850 (Injection, kanamycin sulfate, up to 75 mg); HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1,000 usp units); HCPCS code J7100 (Infusion, dextran 40, 500 ml); and HCPCS code J7110 (Infusion, dextran 75, 500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2024 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2024 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2024 is displayed in Table 39.

BILLING CODE 4120–01–P

TABLE 39: HCPCS CODES TO WHICH THE CY 2024 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2024 HCPCS Code	CY 2024 Long Descriptor	CY 2024 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1020	Injection, methylprednisolone acetate, 20 mg	N
J1030	Injection, methylprednisolone acetate, 40 mg	N
J1040	Injection, methylprednisolone acetate, 80 mg	N
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J2920	Injection, methylprednisolone sodium succinate, up to 40 mg	N
J2930	Injection, methylprednisolone sodium succinate, up to 125 mg	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N
J8520	Capecitabine, oral, 150 mg	N
J8521	Capecitabine, oral, 500 mg	N
J9250	Methotrexate sodium, 5 mg	N
J9260	Methotrexate sodium, 50 mg	N

BILLING CODE 4120–01–C

2. Proposed Payment for Drugs and Biologicals Without Pass-Through Status That Are Not Packaged

a. Proposed Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a ''specified covered outpatient drug'' (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.

• During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and taking into account the hospital acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the ''statutory default.'' Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to take into account overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to take into account the findings of the MedPAC study.[84]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs, but we also are applying this provision to other separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2023.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3-percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug or biological under 1847A(c)(4). We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs and biologicals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

We note that separately payable drug and biological payment rates listed in Addenda A and B to this proposed rule (available on the CMS website[85]), which illustrate the proposed CY 2024 payment based on the ASP methodology for separately payable nonpass-through drugs and biologicals and the ASP methodology for pass-through drugs and biologicals, reflect either ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2023, or WAC, AWP, or mean unit cost from CY 2022 claims data and updated cost report information available for this CY 2024 OPPS/ASC proposed rule. In general, these published payment rates are not the same as the actual January 2024 payment rates. This is because payment rates for drugs and biologicals with ASP information for January 2024 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2023 (July 1, 2023, through September 30, 2023) will be used to set the payment rates that are released for the quarter beginning in January 2024 in December 2023. In addition, payment rates for drugs and

[84] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at: *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.*

[85] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

biologicals in Addenda A and B to this proposed rule, for which there was no ASP, WAC, or AWP information available for April 2023, are based on mean unit cost in the available CY 2022 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2024, we will price payment for these drugs and biologicals based on their newly available information. Finally, there may be drugs and biologicals that have ASP, WAC, or AWP information available for the CY 2024 OPPS/ASC proposed rule (reflecting April 2023 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2024. These drugs and biologicals would then be paid based on mean unit cost data derived from CY 2022 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2024 payment purposes and are only illustrative of the CY 2024 OPPS payment methodology using the most recently available information at the time of issuance of this proposed rule.

For CY 2024, we are not proposing any changes to our policies for payment for separately payable drugs and biologicals; and we are continuing our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

We are, however, proposing to amend the regulation text to reflect our longstanding policies for calculating the Medicare program payment and copayment amounts for separately payable drugs and biologicals by adding a new paragraph (d) to § 419.41.

b. Biosimilar Biological Products

(1) Provisions of the Inflation Reduction Act Relating to Biologicals

The Inflation Reduction Act (Pub. L. 117–169, August 16, 2022) (hereinafter referred to as ''IRA'') contains two provisions that affect payment limits for biosimilar biological products (hereinafter referred to as ''biosimilars''): section 11402 of the IRA amends the payment limit for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available. Section 11403 of the IRA makes changes to the payment limit for certain biosimilars with an ASP that is not more than the ASP of the reference biological for a period of 5 years. We implemented section 11403 of the IRA under program instruction [86] [87], as permitted under section 1847A(c)(5)(C) of the Act.

Section 11402 of the IRA amended section 1847A(c)(4) of the Act by adding subparagraph (B), which limits the payment amount for biosimilars during the initial period described in section 1847A(c)(4)(A). The provision requires that for new biosimilars furnished on or after July 1, 2024, during the initial period when ASP data is not available, the payment limit for the biosimilar is the lesser of (1) an amount not to exceed 103 percent of the WAC of the biosimilar or the Medicare Part B drug payment methodology in effect on November 1, 2003, or (2) 106 percent of the lesser of the WAC or ASP of the reference biological, or in the case of a selected drug during a price applicability period, 106 percent of the maximum fair price of the reference biological. We refer readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulation at § 414.904 to codify section 11402 of the IRA.

Section 11403 of the IRA amended section 1847A(b)(8) of the Act by establishing a temporary payment increase for qualifying biosimilar biological products (hereinafter referred to as ''qualifying biosimilars'') furnished during the applicable 5-year period.[88] Section 1847(b)(8)(B)(iii) of the Act defines ''qualifying biosimilar biological product'' as a biosimilar biological product (as described in section 1847A(b)(1)(C) of the Act) with an ASP (as described in section 1847A(b)(8)(A)(i) of the Act) less than the ASP of the reference biological for a calendar quarter during the applicable 5-year period. Section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference biological's ASP rather than 6 percent during the applicable 5-year period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment. We refer readers to the CY 2024 PFS proposed rule for the discussion of the proposed changes to the regulations at §§ 414.902 and 414.904 to codify section 11403 of the IRA.

Section 1833(t)(14)(A)(iii) of the Act provides for payment of separately covered outpatient drugs (SCODs), and currently, CMS pays under the OPPS for SCODs consistent with the payment methodology set forth in section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default). Through rulemaking, CMS adopted a policy to apply the statutory default payment methodology to separately payable drugs and biologicals that are not SCODs (70 FR 68715 through 68716). Under this authority, the payment rate for SCODs and applicable separately payable drugs and biologicals is determined in accordance with sections 1842(o) and 1847A of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). Because our current policy is to pay for separately payable drugs and biologicals at payment amounts determined under section 1847A, we propose that, for a separately payable biosimilar that is new for purposes of section 1847A(c)(4)(A), the OPPS payment amount would be the amount determined under section 1847A, subject to the payment limit in section 1847A(c)(4)(A). We also propose that, for a separately payable biosimilar that meets the definition of a ''qualifying biosimilar biological product'' for purposes of section 1847A(b)(8)(B)(iii) of the Act, the OPPS payment amount for the biosimilar would be the amount determined under section 1847A, subject to the temporary payment increase under section 1847A(b)(8)(B)(iii). We propose to codify OPPS payment for biosimilars consistent with sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii) by adding new paragraphs (f) and (g) to the regulation at § 419.41. The proposed regulation text cross-references the regulation text included in the PFS proposed rule, which proposes to codify the requirements in sections 1847A(c)(4)(A) and 1847A(b)(8)(B)(iii). We refer readers to the PFS proposed rule for more information about those proposed regulations.

(2) Proposal to Except Biosimilars From the OPPS Packaging Threshold When Their Reference Biologicals Are Separately Paid

Medicare Part B spending for biologicals and biosimilars has

[86] *https://www.cms.gov/files/document/r11496cp.pdf.*

[87] *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice.*

[88] *https://www.congress.gov/bill/117th-congress/house-bill/5376/text?q=%7B%22search%22%3A%5B%22inflation+reduction+act%22%2C%22inflation%22%2C%22reduction%22%2C%22act%22%5D%7D&r=1&s=1.*

significantly outpaced the spending for non-biologic drugs for the past 16 years. According to a 2020 report from the Assistant Secretary for Planning and Evaluation (ASPE), the spending for biologicals and biosimilars represented 77 percent of Medicare Part B prescription drug spending in CY 2017.[89] In a 2020 MedPAC report, the top 10 Part B drugs based on spending were all biologicals, and spending on them in the HOPD represented 39 percent of total HOPD drug spending in CY 2019.[90] Although Part B drug spending for biologicals and biosimilars has grown tremendously in the past 16 years, we also recognize that there is evidence that the entry of biosimilars into the market has contributed to lower aggregate spending for the Medicare program.[91]

Congress has made legislative changes related to payment for biosimilars. First, it amended the Social Security Act to provide for payment of biosimilars in the Affordable Care Act (ACA) and more recently, in the IRA, to update payment for certain biosimilars. In particular, section 3139 of the ACA amended section 1847A(b) by adding a new paragraph (8), which provides that the payment amount for a biosimilar biological product is the biosimilar's ASP and 6 percent of the reference biological's ASP.[92] And as explained previously, section 11402 of the IRA changed the payment limit for biosimilars during the initial period when ASP data is not available and section 11403 of the IRA temporarily increased the payment limit for certain biosimilars.

Our overarching policy goal is to create incentives for efficiency and selection of the least costly products while still meeting a beneficiary's clinical needs and to protect the long-term solvency of the Part B Trust Fund. When we established a policy to pay for biosimilars, we intended to promote the use of biosimilars as a less expensive alternative to their reference biologicals. For CY 2016 and CY 2017, we finalized a policy to pay for biosimilar biological products based on the payment allowance of the product as determined under section 1847A of the Act and to subject nonpass-through biosimilar biological products to our annual threshold-packaged policy (for CY 2016, 80 FR 70445 through 70446; and for CY 2017, 81 FR 79674). In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59351), we explained that, consistent with our established OPPS drug, biological, and radiopharmaceutical payment policy, HCPCS coding for biosimilar biological products will be based on policy established under the CY 2018 PFS final rule with comment period (82 FR 53182 to 53187), where CMS finalized a policy to implement separate HCPCS codes for biosimilar biological products. We also clarified that all biosimilar biological products will be eligible for pass-through payment and not just the first biosimilar biological product for a reference product.

Our threshold packaging policy's intent is to create incentives for efficiency, but we have concerns that packaging biosimilars when the reference biological or other marketed biosimilars are separately paid may create financial incentives for providers to select more expensive, but clinically similar, products. In most cases, a biosimilar either has pass-through status or is separately payable. However, there have been a few instances where biosimilars are packaged. For example, in CY 2021, we noted that HCPCS code Q5105 (Injection, epoetin alfa-epbx, biosimilar, (Retacrit) (for esrd on dialysis), 100 units), was on pass-through status through September 2021. HCPCS code Q5105 is a biosimilar for HCPCS code Q4081 (injection, epoetin alfa, 1000 units (for esrd on dialysis)) and HCPCS code Q4081 is currently packaged under the OPPS. After HCPCS code Q5105's pass-through status expired, payment for HCPCS code Q5105 was packaged because its per day cost fell below our packaging threshold of $130 for CY 2021. In CY 2023, payment for HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) is packaged because its per day cost fell below our packaging threshold of $135 for CY 2023. HCPCS code Q5101 is the biosimilar for HCPCS code J1442 (Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram), which is currently separately payable with a status indicator ''K.''

Packaging payment for both of these biosimilars is consistent with our policy since CY 2018 to subject non-pass through biosimilars to the OPPS threshold-packaging policy. However, we believe this policy may create incentives to use the more expensive reference product or biosimilars that are separately payable, as hospitals would be paid less for using the threshold-packaged biosimilar. For example, the CY 2023 threshold packaging of the biosimilar described by HCPCS code Q5101 (Injection, filgrastim-sndz, biosimilar, (zarxio), 1 microgram) may have created a financial incentive for providers to select the separately paid reference biological or the separately paid filgrastim biosimilar over the packaged filgrastim biosimilar, which is inconsistent with our policy goal of encouraging efficiency and promoting use of biosimilars as lower cost alternatives to their reference biologicals. Accordingly, for CY 2024, we propose to except biosimilars from the OPPS threshold packaging policy when their reference biologicals are separately paid, meaning we would pay separately for these biosimilars even if their per-day cost is below the threshold packaging policy. We believe the threshold packaging exception for biosimilars when their reference biologicals are separately paid would preserve our policy intent to promote biosimilar use as a lower cost alternative to higher cost reference biologicals.

In addition, if a reference product's per-day cost falls below the threshold packaging policy, we propose that all the biosimilars related to the reference product would be similarly packaged regardless of whether their per-day costs are above the threshold. This would allow for consistent treatment of similar biological products in the unusual circumstance in which a biosimilar is priced above the reference biological. For the purpose of identifying biosimilar(s) related to a reference biological product, we would rely on the product's FDA approval under section 351(k) of the Public Health Service Act. For example, filgrastim-sndz (Zarxio), filgrastim-aafi (Nivestym), and filgrastim-ayow (Releuko) are biosimilars related to filgrastim (Neupogen).[93]

(3) Comment Solicitation on Packaging Policy for Reference Biologicals and Biosimilars

[89] Assistant Secretary for Planning and Evaluation. ''Medicare Part B Drugs: Trends in Spending and Utilization, 2006–2017.'' November, 2020. Available at *https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf.*

[90] Medicare Payment Advisory Commission. July 2021 Data Book: Health Care Spending and the Medicare Program. July 2021. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/data-book/july2021_medpac_databook_sec.pdf.*

[91] Medicare Payment Advisory Commission. July 2022 Data Book: Health Care Spending and the Medicare Program. July 2022. Available at *https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_Sec10_v2_SEC.pdf.*

[92] *https://www.congress.gov/111/plaws/publ148/PLAW-111publ148.pdf.*

[93] *https://purplebooksearch.fda.gov/results?query=filgrastim&title=Zarxio.*

While we have proposed to except threshold packaging of biosimilars when their reference biologicals are separately paid in this proposed rule, we are also soliciting comment on the packaging of payment for a reference biological *and* its biosimilar(s) into the payment for the associated service or procedure when the per-day cost of the reference biological, *or* any of its biosimilar(s), is less than or equal to the applicable OPPS drug packaging threshold. While both our proposed policy and the policy described by this comment solicitation share the goal of consistent treatment of similar biologic products, the method to achieve that goal differs. Our proposed policy would result in biosimilars being paid separately if their reference biologic is paid separately, whereas here we seek comment on a policy that would result in packaged payment for a biologic if the reference biologic or any of its biosimilars have per day costs below the drug packaging threshold.

For example, for purposes of this comment solicitation, if a biosimilar's per-day cost is above the threshold and separately paid but its reference product is packaged, the biosimilar (and all its related biosimilar(s)) would be packaged.

Additionally, we seek comment on other ways to structure payment for biologicals and biosimilars that would encourage efficiency while maintaining beneficiary access.

3. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, we are continuing this payment policy for therapeutic radiopharmaceuticals in CY 2024. We pay for separately payable therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals. If ASP methodology (ASP, WAC, and AWP) information is unavailable for a therapeutic radiopharmaceutical, we base therapeutic radiopharmaceutical payment on mean unit cost data derived from hospital claims. The rationale outlined in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) for applying the principles of separately payable drug pricing to therapeutic radiopharmaceuticals continues to be appropriate for nonpass-through, separately payable therapeutic radiopharmaceuticals. Therefore, we are paying for all nonpass-through, separately payable therapeutic radiopharmaceuticals at ASP plus 6 percent (or applicable WAC or AWP amount) based on the statutory default described in section 1833(t)(14)(A)(iii)(II) of the Act. For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521).

Consistent with the policy we adopted for CY 2023 and subsequent years, for CY 2024 we will rely on the most recently available mean unit cost data derived from hospital claims data for payment rates for therapeutic radiopharmaceuticals for which ASP methodology (ASP, WAC, and AWP) data are unavailable and to update the payment rates for separately payable therapeutic radiopharmaceuticals according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP methodology (ASP, WAC, and AWP) information is unavailable. For a complete history of the OPPS payment policy for therapeutic radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

The proposed CY 2024 payment rates for nonpass-through, separately payable therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).[94]

4. Payment for Blood Clotting Factors

For CY 2023, we provided payment for blood clotting factors under the same methodology as other nonpass-through separately payable drugs and biologicals under the OPPS and continued paying an updated furnishing fee (87 FR 71969 through 71970). That is, for CY 2023, we provided payment for blood clotting factors under the OPPS at ASP plus 6 percent, plus an additional payment for the furnishing fee. We note that when blood clotting factors are provided in physicians' offices or other settings for which Medicare makes payment under Part B, a furnishing fee is also applied to the payment. The CY 2023 updated furnishing fee was $0.250 per unit.

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal for CY 2023 and subsequent years to pay for blood clotting factors at ASP plus 6 percent, consistent with our payment policy for other nonpass-through, separately payable drugs and biologicals, and to pay an updated furnishing fee. Our policy to pay a furnishing fee for blood clotting factors under the OPPS is consistent with the methodology applied in the physician's office and in the inpatient hospital setting. These methodologies were first articulated in the CY 2006 OPPS final rule with comment period (70 FR 68661) and later discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765). The proposed furnishing fee update is based on the percentage increase in the Consumer Price Index (CPI) for medical care for the 12-month period ending with June of the previous year. Because the Bureau of Labor Statistics releases the applicable CPI data after the PFS and OPPS/ASC proposed rules are published, we are not able to include the actual updated furnishing fee in the proposed rules. Therefore, in accordance with our policy as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we will announce the actual figure for the percent change in the applicable CPI and the updated furnishing fee calculated based on that figure through applicable program instructions and posting on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/index.html.*

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes But Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. For CY 2024, we will continue to use the same payment policy as in CY 2023 for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during 1 day in the hospital

[94] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

outpatient setting and utilized the ASP methodology to determine their proposed payment status indicators. We refer readers to Table 40 below for the proposed CY 2024 status indicator for each of the nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data which are also listed in Addendum B to this proposed rule, which is available on the CMS website.[95]

BILLING CODE 4120–01–P

[95] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

TABLE 40: DRUGS AND BIOLOGICALS WITHOUT OPPS CLAIMS DATA

CY 2024 HCPCS Code	CY 2024 Long Descriptor	Proposed CY 2024 Status Indicator	Proposed CY 2024 APC
90378	Respiratory syncytial virus monoclonal antibody, recombinant, for intramuscular use, 50 mg, each	K	9003
A9604	Samarium SM-153 lexidronam, therapeutic, per treatment dose, up to 150 millicuries	K	1295
C9488	Injection, conivaptan hydrochloride, 1 mg	K	9488
J0470	injection, dimercaprol, per 100 mg	K	9039
J0691	Injection, lefamulin, 1 mg	K	
J0800	injection, corticotropin, up to 40 units	K	9040
J0879	Injection, difelikefalin, 0.1 microgram, (for esrd on dialysis)	N	9202
J1426	Injection, casimersen, 10 mg	G	9412
J1427	Injection, viltolarsen, 10 mg	K	9386
J1429	Injection, golodirsen, 10 mg	K	9356
J1458	injection, galsulfase, per 5 mg	K	
J1551	Injection, immune globulin (cutaquig), 100 mg	K	9007
J1554	Injection, immune globulin (asceniv), 500 mg	K	9392
J1632	Injection, brexanolone, 1mg	K	9333
J1951	Injection, leuprolide acetate for depot suspension (fensolvi), 1 mg	K	9419
J3031	Injection, fremanezumab-vfrm, 1 mg (code may be used for Medicare when drug administered under the direct supervision of a physician, not for use when drug is self-administered)	K	9197
J3485	injection, zidovudine, 10 mg	E2	
J7181	Factor XIII (antihemophilic factor, recombinant), Tretten, per i.u.	K	
J7203	Injection factor ix, (antihemophilic factor, recombinant), glycopegylated, (rebinyn), 1 iu	K	9468

J7332	Hyaluronan or derivative, triluron, for intra-articular injection, 1 mg	K	
J8705	Topotecan, oral, 0.25 mg	K	
J9019	Injection, asparaginase (erwinaze), 1,000 iu	K	9289
J9210	Injection, emapalumab-lzsg, 1 mg	K	9310
J9348	Injection, naxitamab-gqgk, 1 mg	G	9408
Q0222	Injection, bebtelovimab, 175 mg	K	9401
Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9035
Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	K	9391
Q2055	Idecabtagene vicleucel, up to 460 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9422

BILLING CODE 4120–01–C

6. Proposed OPPS Payment Methodology for 340B Purchased Drugs and Biologicals

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs and biologicals under section 1833(t)(14)(A) of the Act. Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data is not available, the payment amount is the average price for the drug in a year established under section 1842(o) of the Act, which cross-references section 1847A of the Act, which generally sets a default rate of ASP plus 6 percent for certain drugs and biologicals. The provision also provides that the average price for the drug or biological in the year as established under section 1847A of the Act is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). As described below, beginning in CY 2018, the Secretary adjusted the 340B drug payment rate to ASP minus 22.5 percent to approximate a minimum average discount for 340B drugs and biologicals, which was based on findings of the GAO [96] and MedPAC [97] that 340B hospitals were acquiring drugs and biologicals at a significant discount under HRSA's 340B Drug Pricing Program. We direct readers to the CY 2018 OPPS/ASC final rule with comment period for a more detailed discussion of the 340B drug payment policy (82 FR 52493 to 52511).

This policy has been the subject of extensive litigation, including before the Supreme Court of the United States. On June 15, 2022, the Supreme Court held in *American Hospital Association* v. *Becerra,* 142 S. Ct. 1896, that if CMS has not conducted a survey of hospitals' acquisition costs, it may not vary the payment rates for outpatient prescription drugs by hospital group. While the Supreme Court's decision addressed payment rates for CYs 2018 and 2019, it had implications for subsequent payment rates. Therefore, for CY 2023, we finalized a policy to revert to the default payment rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals and finalized a policy to pay for 340B acquired drugs and biologicals no differently than we pay for drugs and biologicals that are not acquired through the 340B program. We also finalized a budget neutrality adjustment to the CY 2023 OPPS conversion factor of 0.9691 percent rather than the 0.9596 percent adjustment we had proposed. This adjustment offset the prior increase of 3.19 percent that was applied to the conversion factor when we implemented the 340B payment policy in CY 2018 in a budget neutral manner and ensured the CY 2023 conversion factor was equivalent to the conversion factor that would be in place if the 340B drug payment policy had never been implemented.

After the publication of the proposed CY 2023 OPPS rule, on September 28, 2022, the District Court issued a final judgment vacating the 340B reimbursement rate for the remainder of 2022, which the District Court explained would automatically reestablish the default rate for 340B-acquired drugs and biologicals. The agency took the necessary steps, including issuing instructions to

[96] Government Accountability Office. ''Medicare Part B Drugs: ''Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals.'' June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[97] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

Medicare contractors and updating drug payment files, to implement that September 28, 2022 decision and has since paid the default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals.[98]

b. Payment for 340B Drugs and Biologicals in CYs 2018 Through 2022

For full descriptions of our OPPS payment policy for drugs and biologicals acquired under the 340B program beginning in CY 2018, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); and the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970 through 71976).

In July, 2023, CMS published a proposed rule, referred to as ''remedy proposed rule'' to address the reduced payment amounts to 340B hospitals under the reimbursement rates in the final OPPS rules for CYs 2018 through 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS. The remedy proposed rule does not propose changes to our CY 2024 OPPS drug payment policy nor the CY 2024 OPPS conversion factor, but it does propose changes to the calculation of the OPPS conversion factor beginning in CY 2025. We believe our proposed remedy rule is consistent with the Supreme Court's decision in *American Hospital Association* and the District Court's remand order. We refer readers to the 340B remedy proposed rule for a full description of this proposed remedy policy as well as for when comments are due to that proposed rule. This document can be found in the **Federal Register** and on the CMS website.[99]

c. CY 2024 Proposed 340B Drug Payment Policy

For CY 2024, consistent with our policy finalized for CY 2023, we propose to continue to pay the statutory default rate, which is generally ASP plus 6 percent, for 340B acquired drugs and biologicals. The payment for 340B acquired drugs and biologicals will not differ from the payment rate for drugs and biologicals not acquired through the 340B program. We believe this policy is appropriate given the Supreme Court decision discussed previously.

In the CY 2023 OPPS/ASC final rule with comment period, we maintained the requirement that 340B hospitals report the ''JG'' (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes*) or ''TB'' (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) modifiers to identify drugs and biologicals acquired through the 340B Program for informational purposes (87 FR 71974). We explained that we believed maintaining both modifiers would reduce provider burden compared to shifting to a single modifier, as all providers can continue utilizing the modifier (either ''JG'' or ''TB'') that they had been using for the previous five calendar years. On December 20, 2022, we issued ''Part B Inflation Rebate Guidance: Use of 340B Modifiers,'' which, in accordance with section 1847A(i) of the Act, requires all 340B covered entities, including hospital-based and non-hospital-based entities, to report the applicable modifier for separately payable drugs and biologicals acquired through the 340B Program.[100] Section 1847A(i) of the Act, as added by the Inflation Reduction Act, requires the Secretary to establish a Part B inflation rebate by manufacturers of certain single source drugs and biologicals with prices increasing faster than the rate of inflation. Section 1847A(i)(3)(B)(ii)(I) of the Act specifically excludes units of drugs and biologicals for which the manufacturer provides a discount under the 340B program from the units of drugs and biologicals for which a manufacturer otherwise may have a Part B inflation rebate liability. Effective implementation of the Part B inflation rebate requires CMS to identify units of drugs and biologicals acquired through the 340B Program so they can be subtracted from the total number of otherwise rebatable units as applicable. This guidance explained that the ''JG'' and ''TB'' modifiers provide an existing mechanism to identify drugs and biologicals acquired through the 340B Program that is familiar to most 340B covered entities paid under the OPPS, and stated that it did not change the requirements in the CY 2023 OPPS/ASC final rule with comment period (*i.e.,* that 340B covered entity hospitals should continue to use the modifiers they used previously to identify 340B drugs and biologicals). For claims with dates of service beginning no later than January 1, 2024, the guidance instructed all 340B covered entities to report the appropriate modifier, including those not currently reporting the ''JG'' or ''TB'' modifier, such as Ryan White clinics and hemophilia clinics, which should report the ''JG'' modifier on separately payable Part B claim lines for drugs and biologicals acquired through the 340B Program.

Although we stated in the CY 2023 OPPS/ASC final rule with comment period and in the ''Part B Inflation Rebate Guidance: Use of 340B Modifiers'' that hospital-based 340B covered entities should continue to use the modifier they used previously (either the ''JG'' or ''TB'' modifier), we now believe utilizing a single modifier will allow for greater simplicity, especially because both modifiers are used for the same purpose: to identify separately payable drugs and biologicals acquired under the 340B Program. Requiring hospitals to report a single modifier would allow CMS to continue to identify and exclude 340B-acquired drugs and biologicals from the definition of units for the purpose of Part B inflation rebate liability, while eliminating the need to use two modifiers for the same purpose. Additionally, we believe this proposal would lessen the burden on providers as they would only have to report one modifier for all scenarios in which a 340B drug is acquired. Accordingly, we propose that all 340B covered entity hospitals paid under the OPPS would report the ''TB'' modifier effective January 1, 2025, even if the hospital previously reported the ''JG'' modifier.

The ''JG'' modifier would remain effective through December 31, 2024. Hospitals that currently report the ''JG'' modifier could choose to continue to use it in CY 2024 or choose to transition to use of the ''TB'' modifier during that year. Beginning on January 1, 2025, the ''JG'' modifier would be deleted and hospitals would be required to report drugs and biologicals acquired through the 340B program using the ''TB'' modifier. Additionally, beginning January 1, 2025, we would revise the ''TB'' modifier descriptor (*Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities*) to no longer include ''. . . *for select entities*'' as all entities would report this modifier after this date. We note that this proposal, if finalized, would update the December 20, 2022, guidance titled ''Part B Inflation Rebate Guidance: Use of the 340B

[98] Vacating Differential Payment Rate for 340B-Acquired Drugs in 2022 Outpatient Prospective Payment System Final Rule with Comment Period. *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

[99] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps.*

[100] *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

Modifiers.'' [101] Additionally, CMS plans to further update this guidance to align the modifier requirements for 340B covered entity providers and suppliers not paid under the OPPS with proposed modifier requirement changes for 340B covered entity hospitals paid under the OPPS.

For more information on the Medicare Part B inflation rebate program, please visit ''*Inflation Rebates in Medicare.*''

7. High Cost/Low Cost Threshold for Packaged Skin Substitutes

a. Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products into their associated surgical procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by HCPCS codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Geometric mean costs for the various procedures are calculated using only claims for the skin substitutes that are assigned to each group. Specifically, claims billed with HCPCS code 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with HCPCS code C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935).

Each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2023, the payment rate for APC 5053 (Level 3 Skin Procedures) was $580.95, the payment rate for APC 5054 (Level 4 Skin Procedures) was $1,725.86, and the payment rate for APC 5055 (Level 5 Skin Procedures) was $3,253.04. This information is also available in Addenda A and B of the CY 2023 final rule with comment period (87 FR 71748) (the final rule and Addenda A and B are available on the CMS website (*https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*)).

We have continued the high cost/low cost categories policy since CY 2014, and we propose to continue it for CY 2024. Under the current policy, skin substitutes in the high-cost category are reported with the skin substitute application CPT codes, and skin substitutes in the low-cost category are reported with the analogous skin substitute HCPCS C-codes. For a discussion of the CY 2014 and CY 2015 methodologies for assigning skin substitutes to either the high-cost group or the low-cost group, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 74932 through 74935) and the CY 2015 OPPS/ASC final rule with comment period (79 FR 66882 through 66885).

For a discussion of the high cost/low cost methodology that was adopted in CY 2016 and has been in effect since then, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434 through 70435). Beginning in CY 2016 and in subsequent years, we adopted a policy where we determined the high cost/low cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC) (the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days) exceeding the PDC threshold. We assigned each skin substitute that exceeded either the MUC threshold or the PDC threshold to the high-cost group. In addition, we assigned any skin substitute with a MUC or a PDC that did not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

However, some skin substitute manufacturers have raised concerns about significant fluctuation in both the MUC threshold and the PDC threshold from year to year using the methodology developed in CY 2016. The fluctuation in the thresholds may result in the reassignment of several skin substitutes from the high-cost group to the low-cost group, which, under current payment rates, can be a difference of over $1,000 in the payment amount for the same procedure. In addition, these interested parties were concerned that the inclusion of cost data from skin substitutes with pass-through payment status in the MUC and PDC calculations would artificially inflate the thresholds. Skin substitute interested parties requested that CMS consider alternatives to the current methodology used to calculate the MUC and PDC thresholds and whether it might be appropriate to establish a new cost group in between the low-cost group and the high-cost group to allow for assignment of moderately priced skin substitutes to a newly created middle group.

We share the goal of promoting payment stability for skin substitute products and their related procedures as price stability allows hospitals using such products to more easily anticipate future payments associated with these products. We have attempted to limit year-to-year shifts for skin substitute products between the high-cost and low-cost groups through multiple initiatives implemented since CY 2014, including: establishing separate skin substitute application procedure codes for low-cost skin substitutes (78 FR 74935); using a skin substitute's MUC calculated from outpatient hospital claims data instead of an average of ASP plus 6 percent as the primary methodology to assign products to the high-cost or low-cost group (79 FR 66883); and establishing the PDC threshold as an alternate methodology to assign a skin substitute to the high-cost group (80 FR 70434 through 70435).

To allow additional time to evaluate concerns and suggestions from interested parties about the volatility of the MUC and PDC thresholds, in the CY 2018 OPPS/ASC proposed rule (82 FR 33627), we proposed that a skin substitute that was assigned to the high-cost group for CY 2017 would be assigned to the high-cost group for CY 2018, even if it did not exceed the CY 2018 MUC or PDC thresholds. We finalized this policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59347). For more detailed information and discussion regarding the goals of this policy and the subsequent comment solicitations in CY 2019 and CY 2020 regarding possible alternative payment methodologies for graft skin substitute products, please refer to the CY 2018 OPPS/ASC final rule with comment period (82 FR

[101] *https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf.*

59347); CY 2019 OPPS/ASC final rule with comment period (83 FR 58967 to 58968); and the CY 2020 OPPS/ASC final rule with comment period (84 FR 61328 to 61331).

b. Proposals for Packaged Skin Substitutes for CY 2024

For CY 2024, consistent with our policy since CY 2016, we propose to continue to determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric MUC exceeding the geometric MUC threshold or the product's PDC (the total units of a skin substitute multiplied by the MUC and divided by the total number of days) exceeding the PDC threshold. Consistent with the methodology as established in the CY 2014 OPPS/ASC through CY 2018 OPPS/ASC final rules with comment period, we analyzed CY 2022 claims data to calculate the MUC threshold (a weighted average of all skin substitutes' MUCs) and the PDC threshold (a weighted average of all skin substitutes' PDCs). The proposed CY 2024 MUC threshold is $47 per cm^2 (rounded to the nearest $1) and the proposed CY 2024 PDC threshold is $817 (rounded to the nearest $1). Also, the availability of a HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271.

For CY 2024, as we did for CY 2023, we propose to assign each skin substitute that exceeds either the MUC threshold or the PDC threshold to the high-cost group. In addition, we propose to assign any skin substitute that does not exceed either the MUC threshold or the PDC threshold to the low-cost group except that we propose that any skin substitute product that was assigned to the high-cost group in CY 2023 would be assigned to the high-cost group for CY 2024, regardless of whether it exceeds or falls below the CY 2024 MUC or PDC threshold. This policy was established in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59346 through 59348).

For CY 2024, we propose to continue to assign skin substitutes with pass-through payment status to the high-cost category. We propose to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high-cost or low-cost category. We propose to continue to use WAC plus 3 percent instead of WAC plus 6 percent to conform to our proposed policy described in section V.B.2.b of this proposed rule to establish a payment rate of WAC plus 3 percent for separately payable drugs and biologicals that do not have ASP data available. We propose that any skin substitute product that is assigned a code in the HCPCS A2XXX series would be assigned to the high-cost skin substitute group including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds. For a discussion of our existing policy under which we assign skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series to the low-cost category until pricing information is available, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70436).

Table 41 includes the proposed CY 2024 cost category assignment for each skin substitute product.

BILLING CODE 4120–01–P

TABLE 41: SKIN SUBSTITUTE ASSIGNMENTS TO HIGH-COST AND LOW-COST GROUPS FOR CY 2024

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
A2001	Innovamatrix ac, per sq cm	High	High
A2002	Mirragen adv wnd mat per sq	High	High
A2005	Microlyte matrix, per sq cm	High	High
A2006	Novosorb synpath per sq cm	High	High
A2007	Restrata, per sq cm	High	High
A2008	Theragenesis, per sq cm	High	High
A2009	Symphony, per sq cm	High	High
A2010	Apis, per square centimeter	High	High
A2011	Supra sdrm, per sq cm	High	High
A2012	Suprathel, per sq cm	High	High
A2013	Innovamatrix fs, per sq cm	High	High
A2015	Phoenix wnd mtrx, per sq cm	High	High
A2016	Permeaderm b, per sq cm	High	High
A2017	Permeaderm glove, each	High	High
A2018	Permeaderm c, per sq cm	High	High
A2019	kerecis marigen shld sq cm	High	High
A2020	ac5 wound system	High	High
A2021	neomatrix per sq cm	High	High
A4100	Skin sub fda clrd as dev nos	Low	Low
C9363	Integra meshed bil wound mat	High	High
Q4100	Skin substitute, nos	Low	Low
Q4101	Apligraf	High	High
Q4102	Oasis wound matrix	Low	Low
Q4103	Oasis burn matrix	High	High*
Q4104	Integra bmwd	High	High
Q4105	Integra drt or omnigraft	High	High*
Q4106	Dermagraft	High	High
Q4107	Graftjacket	High	High
Q4108	Integra matrix	High	High
Q4110	Primatrix	High	High
Q4111	Gammagraft	Low	Low
Q4115	Alloskin	Low	Low
Q4116	Alloderm	High	High
Q4117	Hyalomatrix	Low	Low
Q4121	Theraskin	High	High*
Q4122	Dermacell	High	High
Q4123	Alloskin	High	High
Q4124	Oasis tri-layer wound matrix	Low	Low

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4126	Memoderm/derma/tranz/integup	High	High
Q4127	Talymed	High	High*
Q4128	Flexhd/allopatchhd/matrixhd	High	High
Q4132	Grafix core, grafixpl core	High	High
Q4133	Grafix stravix prime pl sqcm	High	High
Q4134	Hmatrix	High	High*
Q4135	Mediskin	Low	High
Q4136	Ezderm	Low	Low
Q4137	Amnioexcel biodexcel, 1 sq cm	High	High
Q4138	Biodfence dryflex, 1cm	High	High
Q4140	Biodfence 1cm	High	High
Q4141	Alloskin ac, 1cm	High	High*
Q4143	Repriza, 1cm	High	High
Q4146	Tensix, 1cm	High	High
Q4147	Architect ecm px fx 1 sq cm	High	High
Q4148	Neox rt or clarix cord	High	High
Q4150	Allowrap ds or dry 1 sq cm	High	High
Q4151	Amnioband, guardian 1 sq cm	High	High
Q4152	Dermapure 1 square cm	High	High
Q4153	Dermavest, plurivest sq cm	High	High
Q4154	Biovance 1 square cm	High	High
Q4156	Neox 100 or clarix 100	High	High
Q4157	Revitalon 1 square cm	High	High*
Q4158	Kerecis omega3, per sq cm	High	High
Q4159	Affinity 1 square cm	High	High
Q4160	Nushield 1 square cm	High	High
Q4161	Bio-connekt per square cm	High	High
Q4163	Woundex, bioskin, per sq cm	High	High
Q4164	Helicoll, per square cm	High	High*
Q4165	Keramatrix, per square cm	Low	Low
Q4166	Cytal, per square centimeter	Low	Low
Q4167	Truskin, per square centimeter	High	High
Q4169	Artacent wound, per sq cm	High	High
Q4170	Cygnus, per sq cm	High	High
Q4173	Palingen or palingen xplus	High	High
Q4175	Miroderm, per square cm	High	High
Q4176	Neopatch, per sq centimeter	High	High
Q4178	Floweramniopatch, per sq cm	High	High
Q4179	Flowerderm, per sq cm	High	High*
Q4180	Revita, per sq cm	High	High
Q4181	Amnio wound, per square cm	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4182	Transcyte, per sq centimeter	High	High*
Q4183	Surgigraft, 1 sq cm	High	High*
Q4184	Cellesta or duo per sq cm	High	High
Q4186	Epifix 1 sq cm	High	High
Q4187	Epicord 1 sq cm	High	High
Q4188	Amnioarmor 1 sq cm	High	High
Q4190	Artacent ac 1 sq cm	High	High
Q4191	Restorigin 1 sq cm	High	High
Q4193	Coll-e-derm 1 sq cm	High	High
Q4194	Novachor 1 sq cm	High	High*
Q4195	Puraply 1 sq cm	High	High
Q4196	Puraply am 1 sq cm	High	High
Q4197	Puraply xt 1 sq cm	High	High
Q4198	Genesis amnio membrane 1 sq cm	High	High
Q4199	Cygnus matrix, per sq cm	High	High
Q4200	Skin te 1 sq cm	High	High
Q4201	Matrion 1 sq cm	High	High
Q4203	Derma-gide, 1 sq cm	High	High
Q4204	Xwrap 1 sq cm	Low	Low
Q4205	Membrane graft or wrap sq cm	High	High
Q4208	Novafix per sq cm	High	High
Q4209	Surgraft per sq cm	High	High*
Q4210	Axolotl graf dualgraf sq cm	High	High
Q4211	Amnion bio or axobio sq cm	High	High
Q4214	Cellesta cord per sq cm	Low	Low
Q4216	Artacent cord per sq cm	Low	Low
Q4217	Woundfix biowound plus xplus	High	High
Q4218	Surgicord per sq cm	Low	High
Q4219	Surgigraft dual per sq cm	High*	High*
Q4220	Bellacell HD, Surederm sq cm	Low	Low
Q4221	Amniowrap2 per sq cm	Low	Low
Q4222	Progenamatrix, per sq cm	High	High*
Q4224	Hhf10-p per sq cm	Low	Low
Q4225	Amniobind, per sq cm	Low	Low
Q4226	Myown harv prep proc sq cm	High	High*
Q4227	Amniocore per sq cm	High	High
Q4228	Bionextpatch, per sq cm	Low	Low
Q4229	Cogenex amnio memb per sq cm	High	High*
Q4232	Corplex, per sq cm	High	High
Q4234	Xcellerate, per sq cm	High	High

CY 2024 HCPCS Code	CY 2024 Short Descriptor	CY 2023 High/Low Cost Assignment	CY 2024 High/Low Cost Assignment
Q4235	Amniorepair or altiply sq cm	High	High
Q4236	Carepatch per sq cm	Low	Low
Q4237	cryo-cord, per sq cm	High	High
Q4238	Derm-maxx, per sq cm	High	High
Q4239	Amnio-maxx or lite per sq cm	High	High
Q4247	Amniotext patch, per sq cm	Low	Low
Q4248	Dermacyte Amn mem allo sq cm	High	High
Q4249	Amniply, per sq cm	High	High
Q4250	AmnioAMP-MP per sq cm	Low	High
Q4253	Zenith amniotic membrane psc	Low	High
Q4254	Novafix dl per sq cm	High	High*
Q4255	Reguard, topical use per sq	Low	Low
Q4256	Mlg complet, per sq cm	Low	Low
Q4257	Relese, per sq cm	Low	Low
Q4258	Enverse, per sq cm	High	High*
Q4259	Celera per sq cm	Low	Low
Q4260	Signature apatch, per sq cm	Low	Low
Q4261	Tag, per square centimeter	Low	Low
Q4262	Dual layer impax, per sq cm	Low	Low
Q4263	Surgraft tl, per sq cm	Low	Low
Q4264	Cocoon membrane, per sq cm	Low	Low
Q4265	Neostim tl per sq cm	Low	Low
Q4266	Neostim per sq cm	Low	Low
Q4267	Neostim dl per sq cm	Low	Low
Q4268	Surgraft ft per sq cm	Low	Low
Q4269	Surgraft xt per sq cm	Low	Low
Q4270	Complete sl per sq cm	Low	Low
Q4271	Complete ft per sq cm	Low	Low

* These products do not exceed either the MUC or PDC threshold for CY 2024 but are assigned to the high-cost group because they were assigned to the high-cost group in CY 2023.

BILLING CODE 4120–01–C

8. Radioisotopes Derived From Non-Highly Enriched Uranium (Non-HEU) Sources

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Some of the Technetium-99 (Tc-99m), the radioisotope used in the majority of such diagnostic imaging services, has been produced in legacy reactors outside of the United States using highly enriched uranium (HEU).

The United States wanted to eliminate domestic reliance on these reactors and has been promoting the conversion of all medical radioisotope production to non-HEU sources. Alternative methods for producing Tc-99m without HEU are technologically and economically viable, but it was expected that this change in the supply source for the radioisotope used for modern medical imaging would introduce new costs into the payment system that were not accounted for in the historical claims data.

Therefore, beginning in CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals report HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose along with any diagnostic scan or scans furnished using Tc-99m as long as the Tc-99m doses used can be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

We stated in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68321) that our expectation was that this additional payment would be needed for the duration of the industry's conversion to alternative methods of producing Tc-99m without HEU. We

also stated that we would reassess, and propose if necessary, on an annual basis whether such an adjustment continued to be necessary and whether any changes to the adjustment were warranted (77 FR 68321). A 2016 report from the National Academies of Sciences, Engineering, and Medicine anticipated the conversion of Tc-99m production from non-HEU sources would be completed at the end of 2019.[102] However, the Secretary of Energy issued a certification effective January 2, 2020, stating that there continued to be an insufficient global supply of molybdenum-99 (Mo-99), which is the source of Tc-99m, produced without the use of HEU, available to satisfy the domestic U.S. market (85 FR 3362). The January 2, 2020 certification was to remain in effect for up to 2 years.

The Secretary of Energy issued a new certification regarding the supply of non-HEU-sourced Mo-99 effective January 2, 2022 (86 FR 73270). This certification stated that there was a sufficient global supply of Mo-99 produced without the use of HEU available to meet the needs of patients in the United States. The Department of Energy also expected that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022. In CY 2019, we stated that we would reassess the non-HEU incentive payment policy once conversion to non-HEU sources is closer to completion or has been completed (83 FR 58979). There is now a sufficient supply of non-HEU-sourced Mo-99 in the United States, and there is no available supply of HEU-sourced Mo-99 in the United States. In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the conversion to non-HEU sources of Tc-99m had reached a point where it was necessary to reassess our policy of providing an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (87 FR 71987).

In the OPPS, diagnostic radiopharmaceuticals are packaged into the cost of the associated diagnostic imaging procedure no matter the per day cost of the radiopharmaceutical. The cost of the radiopharmaceutical is included as a part of the cost of the diagnostic imaging procedure and is reported through Medicare claims data. Medicare claims data used to set payment rates under the OPPS generally is from 2 years prior to the payment year.

As we explained in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71987), the claims data we would use to set payment rates for CY 2024 (likely CY 2022 claims data) contain claims for diagnostic radiopharmaceuticals that reflect both HEU-sourced Tc-99m and non-HEU-sourced Tc-99m, rather than radiopharmaceuticals sourced solely from non-HEU Tc-99m. The cost of HEU-sourced Tc-99m is substantially lower than the cost of non-HEU-sourced Tc-99m. Therefore, we explained that providers who use radiopharmaceuticals in CY 2024 that contain only non-HEU-sourced Tc-99m might not receive a payment that is reflective of the radiopharmaceutical's current cost without the add-on payment. We believed that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2024 would ensure adequate payment for non-HEU-sourced Tc-99m. Starting in CY 2025, we believed the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a result, we believed there would no longer be a need for the additional $10 add-on payment for CY 2025 or future years.

This policy was based on the Secretary of Energy's certification that the last HEU reactor that produces Mo-99 for medical providers in the United States would finish its conversion to a non-HEU reactor by December 31, 2022, and that all Tc-99m used for radiopharmaceuticals in 2023 would be produced from non-HEU sources. However, we understand that the conversion of the last HEU reactor that produces Tc-99m to a non-HEU reactor did not occur until March 2023, so it is possible that some claims for diagnostic radiopharmaceuticals in CY 2023 would report the cost of HEU-sourced Tc-99m. This means that in CY 2025, as in CY 2024, there is the possibility that the payment rate for procedures using diagnostic radiopharmaceuticals could be lower than the costs providers will face for these procedures because providers will only have access to non-HEU-sourced Tc-99m.

We believe that extending the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 rather than the end of CY 2024, as we previously finalized, would ensure adequate payment for non-HEU-sourced Tc-99m now that the conversion from HEU-sourced Tc-99m to non-HEU-sourced Tc-99m is complete. Starting in CY 2026, the Medicare claims data utilized to set payment rates (likely CY 2024 claims data) will only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, which means the data will more closely reflect the cost of the Tc-99m diagnostic radiopharmaceuticals that will be used by providers in CY 2026. As a result, there will no longer be a need for the additional $10 add-on payment for CY 2026 or future years.

We propose to continue the additional $10 payment through December 31, 2025, as beginning in CY 2026, the Medicare claims data used to set payment rates will reflect the full cost of non-HEU-sourced Tc-99m.

C. Requirement in the Physician Fee Schedule CY 2024 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 notice in the OPPS/ASC proposed rule (87 FR 71988), we want to ensure interested parties are aware of these proposals and know to refer to the Physician Fee Schedule (PFS) proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals related to implementation of section 90004 of the Infrastructure Act on the CY 2024 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appears in section XIII.D.3 of this proposed rule.

[102] National Academies of Sciences, Engineering, and Medicine. 2016. Molybdenum-99 for Medical Imaging. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23563*.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an ''applicable percentage,'' currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2024 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2024. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2023 or beginning in CY 2024. The sum of the proposed CY 2024 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2024 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2014 OPPS/ASC final rule with comment period (78 FR 75034 through 75036). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), in the proposed rule, we proposed to include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2024, we also propose to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary determines is associated with the drug or biological. Consistent with current policy, we propose to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2024, and therefore our estimate of drug and biological pass-through payment for CY 2024 for this group of items is $100 million.

Payment for certain drugs, specifically diagnostic radiopharmaceuticals and contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package all non pass-through drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, drugs and biologicals that function as supplies when used in a surgical procedure, drugs and biologicals used for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c of this proposed rule. Consistent with current policy, propose that all of these policy-packaged drugs and biologicals with pass-through payment status would generally be paid at ASP plus 6 percent, like other pass-through drugs and biologicals, for CY 2024, less the policy-packaged drug APC offset amount described below. Our estimate of passthrough payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2024 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In section V.A.6 of this proposed rule, we discuss our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the costs of the APCs that are associated with the drug receiving passthrough payment, we propose to offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2024. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in the remaining quarters of CY 2023 or beginning in CY 2024. The sum of the CY 2024 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2024 pass-through spending estimate for

drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2024

For CY 2024, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2024, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2023 (87 FR 719889). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2024, there are 7 active categories for CY 2024. The active categories are described by HCPCS codes C1747, C1761, C1826, C1827, C1831, C1832, and C1833. Based on the information from the device manufacturers, we estimate that HCPCS code C1747 will cost $37.5 million in pass-through expenditures in CY 2024, HCPCS code C1761 will cost $19.6 million in pass-through expenditures in CY 2024, HCPCS code C1826 will cost $7.4 million in pass-through expenditures in CY 2024, HCPCS code C1827 will cost $28.8 million in pass-through expenditures in CY 2024, HCPCS code C1831 will cost $163,436 in pass-through expenditures in CY 2024, HCPCS code C1832 will cost $37,603 in pass-through expenditures in CY 2024, and HCPCS code C1833 will cost $281,238 in pass-through expenditures in CY 2024. Therefore, we propose an estimate for the first group of devices of $93.7 million.

In estimating our proposed CY 2024 pass-through spending for device categories in the second group, we included: device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2024; additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2024; and contingent projections for new device categories established in the second through fourth quarters of CY 2024. For CY 2024, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the proposed estimate of CY 2024 pass-through spending for this second group of device categories is $40.4 million.

To estimate proposed CY 2024 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2024, we propose to use the CY 2022 Medicare hospital outpatient claims data regarding their utilization, information provided in the respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2024 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged diagnostic radiopharmaceuticals, contrast agents, drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will continue to have pass-through payment status in CY 2024, we estimate the pass-through payment amount as the difference between ASP plus 6 percent and the payment rate for non pass-through drugs and biologicals that will be separately paid. Because we propose to apply a payment rate of ASP plus 6 percent to most drugs and biologicals in this proposed rule, the proposed payment rate difference between the pass-through payment amount and the non pass-through payment amount is $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2024 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP plus 6 percent (or WAC plus 6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug receiving pass-through payment, which we estimate for CY 2024 for the first group of policy-packaged drugs to be $90 million.

To estimate proposed CY 2024 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2023, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2024, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2024), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per-unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2024 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2024 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2024 and those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2024 would be approximately $234.1 million (approximately $134.1 million for device categories and approximately $100 million for drugs and biologicals) which represents 0.26 percent of total projected OPPS payments for CY 2024 (approximately $88.6 billion). Therefore, we estimate that pass-through spending in CY 2024 would not amount to 2.0 percent of total projected OPPS CY 2024 program spending.

VII. Proposed OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2024, we propose to continue our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70448). We also propose to continue our payment policy for critical care services for CY 2024. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70449), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final

rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by non-excepted off-campus provider-based departments (PBDs) applies for CY 2023 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2023 and beyond. The PFS-equivalent rate for CY 2024 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2024.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus provider-based departments (PBDs) (departments that bill the modifier ''PO'' on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024, we propose to continue to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy. We will continue to monitor the effect of this change in Medicare payment policy, including on the volume of these types of OPD services.

VIII. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses proposed payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare will begin paying for intensive outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers and rural health clinics. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Partial Hospitalization

1. Background

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

Partial hospitalization program policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176) and instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer readers to section X.B of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 through 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016, we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers and renumbered the PHP APCs. In CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for

hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381, and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, so long as the location meets all conditions of participation to the extent not waived. A hospital or CMHC can furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary is registered as an outpatient. In the CY 2023 OPPS/ASC final rule (87 FR 72247), we confirmed these provisions as final, including that they apply only for the duration of the COVID–19 PHE. On May 11, 2023, the COVID–19 PHE ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. Since the final calculated geometric mean per diem costs for both CMHCs and hospital-based PHPs were significantly higher than each proposed cost floor, a floor was not necessary at the time, and we did not finalize the proposed cost floors in the CY 2021 OPPS/ASC final rule with comment period.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666), we explained that we observed a number of changes, likely as a result of the COVID–19 PHE, in the CY 2020 OPPS claims that we would have ordinarily used for CY 2022 ratesetting, and this included changes in the claims for partial hospitalization. We explained that significant decreases in utilization and in the number of hospital-based PHP providers who submitted CY 2020 claims led us to believe that CY 2020 data were not the best overall approximation of expected PHP services in CY 2022. Therefore, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we explained that we continued to observe a decrease in the number of hospital-based and CMHC PHP days in our trimmed dataset due to the continued effects of COVID–19, however, the Medicare outpatient service volumes appeared to be returning to more normal, pre-pandemic levels. Therefore, we finalized our proposal to use the latest available CY 2021 claims, but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, in the interest of accurately paying for CMHC PHP services, under the unique circumstances of budget neutralizing all other OPPS policy changes for CY 2023, and in keeping with our longstanding goal of protecting continued access to PHP services provided by CMHCs by ensuring that CMHCs remain a viable option as providers of mental health care in the beneficiary's own community, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, $142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital would not be recognized as PHP services, however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

Section 4124(a) of Division FF of the CAA, 2023 amends section 1861(ff)(1) of the Act to modify the definition of partial hospitalization services furnished on or after January 1, 2024. Specifically, section 4124(a) of the CAA, 2023 amends section 1861(ff)(1) of the Act by adding to the current definition that partial hospitalization services are ''for an individual determined (not less frequently than monthly) by a physician to have a need for such services for a minimum of 20 hours per week.'' We discuss these revisions to the definition of partial hospitalization services in the following section, section VIII.A.2, of this proposed rule.

2. Revisions to PHP Physician Certification Requirements

As amended by section 4124(a) of the CAA, 2023, section 1861(ff)(1) requires that a physician determine that each patient needs a minimum of 20 hours of PHP services per week, and this determination must occur no less frequently than monthly. We propose to codify this requirement in regulation as an additional requirement for the physician certification applicable for PHP services that we would add to § 424.24(e)(1)(i). We are not proposing any changes to the existing physician certification requirements for PHP, including that the patient would require inpatient hospitalization if they did not

receive PHP services, which would remain at § 424.24(e)(1)(i).

Existing regulations at § 410.43 set forth conditions and exclusions that apply for partial hospitalization services. Under § 410.43(a)(3), partial hospitalization services are services that are furnished in accordance with a physician certification and plan of care as specified under § 424.24(e). Additionally, current patient eligibility criteria at § 410.43(c)(1) state that partial hospitalization programs are intended for patients who require a minimum of 20 hours per week of therapeutic services as evidenced in their plan of care. Because partial hospitalization services are already required to be furnished in accordance with a physician certification and plan of care, we believe it is appropriate to include this 20-hour minimum weekly requirement as a physician certification requirement at § 424.24(e)(1)(i). We note that we do not believe this proposed change to the regulation would create a new requirement for PHPs from a practical perspective, as the change to the definition of partial hospitalization services made by the CAA, 2023 is consistent with the longstanding 20-hour minimum weekly regulatory requirement at § 410.43(c)(1) that Medicare has applied to PHP.

We propose to modify the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services include a certification that the patient requires such services for a minimum of 20 hours per week. Current regulations at § 424.24(e)(3)(ii) require an initial recertification after 18 days, with subsequent recertifications of PHP services no less frequently than every 30 days. We believe this interval is consistent with the CAA, 2023 requirement that the physician's determination of the need for PHP services at least 20 hours per week must occur no less frequently than monthly.

B. Intensive Outpatient Program Services

1. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. Section 4124(b)(1)(A) of the CAA, 2023 amended section 1832(a)(2)(J) of the Act to add intensive outpatient services to the scope of covered benefits provided by CMHCs, and section 4124(b)(1)(B) amended section 1861(s)(2)(B) to add intensive outpatient services to the definition of ''medical and other health services'', specifically, as a service furnished ''incident to a physicians' services.''

Intensive outpatient services are furnished under an intensive outpatient program (IOP). Similar to PHP, an IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders. Generally speaking, an IOP is thought to be less intensive than a PHP, and the statutory definition of IOP services reflects this difference in intensity. Specifically, section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add a new paragraph (4) to define the term ''intensive outpatient services'' as having the same meaning as ''partial hospitalization services'' in paragraph (1). In particular, intensive outpatient services are the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. For patients of an IOP, section 1835(a)(2)(F)(i) of the Act does not apply, that is, individuals receiving IOP would not require inpatient psychiatric care in the absence of such services. Lastly, section 4124(b)(2)(B) of the CAA, 2023 further added to section 1861(ff)(4)(C), which cross-references paragraph (3), that an IOP is a program furnished by a hospital to its outpatients, or by a community mental health center (CMHC), a Federally qualified health center (FQHC), or a rural health clinic (RHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 4124(c) of the CAA, 2023 amends section 1834 of the Act by adding a new paragraph (5) to subsection (o) and a new paragraph (3) to subsection (y), which include special payment rules for intensive outpatient services furnished in FQHCs and RHCs, which are discussed in greater detail in section VIII.F of this proposed rule.

This proposed rule includes proposals to establish payment and program requirements for the IOP benefit in all of the above-described settings. Section VIII.B.2 of this proposed rule discusses the proposed scope of benefits for IOP services, and section VIII.B.3 of this proposed rule discusses proposed physician certification requirements. Section VIII.C of this proposed rule discusses proposed coding and billing for both PHP and IOP services under the OPPS beginning in CY 2024. Section VIII.D of this proposed rule discusses the proposed payment methodology. Section VIII.E of this proposed rule discusses proposed outlier policy for CMHCs. Section VIII.F of this proposed rule discusses proposed payment for IOP in FQHCs and RHCs, and Section VIII.G of this proposed rule discusses proposed payment for IOP in Opioid Treatment Programs (OTPs).

2. IOP Scope of Benefits

Section 1861(ff)(2) of the Act describes the items and services available under the IOP benefit. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the

reasonable expectation of patient improvement.

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we propose to add regulations at 42 CFR 410.44 to set forth the conditions and exclusions that would apply for intensive outpatient services. Consistent with the existing regulations for partial hospitalization services, we propose to require that intensive outpatient services must be furnished in accordance with a physician certification and plan of care. However, where partial hospitalization requires the physician to certify that the services are instead of inpatient hospitalization, intensive outpatient program services are not intended for those who otherwise need an inpatient level of care. That is, section 1861(ff)(4)(A) of the Act, as added by section 4124 of the CAA, 2023, states that for intensive outpatient services, section 1835(a)(2)(F)(i) shall not apply. As further discussed in section VIII.B.3 of this proposed rule, we propose to add language to the regulation at § 424.24(d), which is currently reserved, that would set forth the physician certification and plan of care requirements for intensive outpatient services.

Additionally, we propose to revise certain existing regulations at § 410.2, § 410.3, § 410.10, § 410.27, § 410.150, and § 419.21 to add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. We propose to create regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we propose to revise § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023. We discuss these proposed changes in the following paragraphs.

a. Proposed Definition of Intensive Outpatient Services

We propose the following definition at § 410.2 for intensive outpatient services: Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. We note that the proposed definition for intensive outpatient services is consistent with the statutory requirements of section 1861(ff)(3)(A), which apply to both IOP and PHP services. Accordingly, the proposed definition is largely consistent with the existing regulatory definition of partial hospitalization services. However, in accordance with section 1861(ff)(4)(A) of the Act, as added by the CAA, 2023, we are including a clarification in the regulatory definition of ''intensive outpatient services'' that they are not required to be provided in lieu of inpatient hospitalization. We are including this clarification in order to more clearly differentiate between the definitions of partial hospitalization and intensive outpatient at § 410.2.

The conditions and exclusions for partial hospitalization services are included in the regulation at § 410.43. We propose that the conditions and exclusions for intensive outpatient services would be included in new regulations at § 410.44.

At new § 410.44, we propose to establish regulatory language for intensive outpatient services that is consistent with the existing language for partial hospitalization conditions and exclusions and the statutory definition of intensive outpatient services. Specifically, under § 410.44(a) we propose that IOP services are services that: (1) are reasonable and necessary for the diagnosis or active treatment of the individual's condition; (2) are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; (3) are furnished in accordance with a physician certification and plan of care as specified under new regulations at § 424.24(d); and include any of the services listed in § 410.44(a)(4). Under § 410.44(a)(4), we include a list of the types of services that we propose would be covered as intensive outpatient services:

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.
- Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.
- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.
- Individualized activity therapies that are not primarily recreational or diversionary.
- Family counseling, the primary purpose of which is treatment of the individual's condition.
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.
- Diagnostic services.

The proposed list at § 410.44(a)(4) is based on the list of items and services described in section 1861(ff)(2) of the Act. We note that 1861(ff)(2) of the Act also provides that intensive outpatient services may include such other items and services as the Secretary may provide (but in no event to include meals and transportation). As discussed in section VIII.C of this proposed rule, we solicit comments on whether additional codes should be added to the list of services recognized as appropriate for PHP and IOP.

We further note that both the statute at section 1861(ff)(2)(C) of the Act and our proposed regulation at § 410.44(a)(4)(iii) refer to ''trained psychiatric nurses, and other staff trained to work with psychiatric patients.'' Under our longstanding policy for partial hospitalization services, we have considered nurses and other staff trained to work with patients within their state scope of practice who are receiving treatment for substance use disorder (SUD) to be included under this statutory definition and the regulatory definition of PHP at § 410.43(a)(4). We have heard from interested parties that there could be a misconception that Medicare does not cover PHP for the treatment of SUD. We are clarifying that, in general, notwithstanding the requirement that PHP services are provided in lieu of inpatient hospitalization, Medicare covers PHP for the treatment of SUD, and we consider services that are for the treatment of SUD and behavioral health generally to be consistent with the statutory and regulatory definition of PHP. We are taking this opportunity to clarify that the terms ''trained psychiatric nurses, and other staff trained to work with psychiatric patients,'' as used in § 410.43(a)(4) and § 410.44(a)(4) would include trained SUD nurses and other staff trained to work with SUD patients. Under § 410.44(b), we propose that the following services are separately covered and not paid as intensive

outpatient services: (1) physician services; (2) physician assistant services; (3) nurse practitioner and clinical nurse specialist services; (4) qualified psychologist services; and (5) services furnished to residents of a skilled nursing facility (SNF). We note that these proposed exclusions are consistent with the services excluded from payment as partial hospitalization program services at § 410.43(b). The services listed under §§ 410.43(b) and 410.44(b) would be paid under the applicable systems for such services.

Lastly, under § 410.44(c), we propose to establish patient eligibility criteria for intensive outpatient services. Specifically, we propose that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

We note that these proposed patient eligibility criteria at § 410.44(c) are consistent with the existing partial hospitalization patient eligibility criteria at § 410.43(c). With respect to the proposed criterion of a ''mental health diagnosis'', we are clarifying that a mental health diagnosis would include SUD and behavioral health diagnoses generally under both the existing partial hospitalization regulation at § 410.43(c)(5) and the proposed intensive outpatient services regulation at § 410.44(c)(5). As discussed earlier in this section, this inclusion of SUD and behavioral health diagnoses as among the patient eligibility criteria for PHP services is consistent with our longstanding policy. However, we have noted that interested parties have raised concerns that this policy may not be clear. Therefore, we are clarifying that the term ''mental health diagnosis'' as used at both §§ 410.43(c)(5) and 410.44(c)(5) would include SUD and behavioral health diagnoses.

b. Coverage of IOP as Medical and Other Health Services Paid Under Part B

We propose to amend the regulation at § 410.10(c) to add a reference to ''intensive outpatient services'' to the list of services that are covered as medical and other health services under Part B, when furnished as hospital or CAH services incident to a physician's professional services. We believe this is consistent with section 1861(s)(2)(B) of the Act, as amended by section 4124(b)(1)(B) of the CAA, 2023 to include ''intensive outpatient services'' under the definition of medical and other health services; specifically, hospital services incident to a physicians' services. We note that the services described at § 410.10(c) are furnished by a hospital or CAH. Accordingly, we propose conforming changes to the regulations at §§ 410.27(a)(2) and paragraph (e) introductory text to include references to intensive outpatient services.

c. Technical Changes To Codify Requirements for IOP at CMHCs

We propose technical changes to the regulations at 42 CFR parts 488 and 489.

First, we propose to add the statutory basis for IOP at CMHCs at § 488.2. The proposed technical revision would add section 1832(a)(2)(J) of the Act, which sets forth the statutory basis of intensive outpatient services provided by CMHCs at § 488.2.

We also propose to revise the provision at 42 CFR 489.2(c)(2) so that CMHCs may enter into provider agreements to furnish intensive outpatient services. We propose to revise the current requirement that allows for CMHCs to enter into provider agreements only for the provision of partial hospitalization services. The proposed revisions to this provision would allow CMHCs to enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

d. Technical Changes To Codify Coverage of IOP at CMHCs

We propose several technical changes and additions to the regulations at §§ 410.2, 410.3, 410.111, and 410.150.

First, we propose to revise the definition of ''Community Mental Health Center (CMHC)'' at § 410.2 to refer to intensive outpatient services. Specifically, we propose to revise the regulation to state that a CMHC is an entity that provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services. Second, we propose to revise the definition of ''Participating'' at § 410.2 to refer to intensive outpatient services as services that CMHCs can provide. Specifically, we propose that ''Participating'' refers to a CMHC that has in effect an agreement to participate in Medicare, but only for the purposes of providing partial hospitalization services and intensive outpatient services. We are clarifying that this proposed definition would allow a CMHC to be considered a participating provider of both partial hospitalization services and intensive outpatient services, but would not require a CMHC to provide both types of services in order to be considered participating.

In addition, we propose to revise the scope of benefits provision at § 410.3(a)(2) to provide that the covered services for which the Medicare Part B supplementary medical insurance (SMI) program helps pay include partial hospitalization services and intensive outpatient services provided by CMHCs. We believe these proposed changes are consistent with the scope of benefits provision at section 1832(a)(2)(J) of the Act, as amended by section 4124(b)(1)(A) of the CAA, 2023 to include intensive outpatient services, as well as the proposed CMHC conditions of participation at § 485.918(b)(1)(iii). We refer readers to section XVII.B.5 of this proposed rule for discussion on the proposed amendments to regulations at § 485.918(b)(1)(iii).

In addition, subpart E of § 410 includes requirements for Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services. We propose to modify the Subpart E heading to include a reference to intensive outpatient services as well. Under subpart E, we propose to add a new § 410.111 to set forth Requirements for coverage of intensive outpatient services furnished in CMHCs. We propose that Medicare Part B would cover IOP services furnished by or under arrangements made by a CMHC if the CMHC has in effect a provider agreement and the services are prescribed by a physician and furnished under the general supervision of a physician, and subject to the proposed physician certification and plan of care requirements under § 424.24(d).

Additionally, we propose to revise § 410.150(b)(13) to include a reference to intensive outpatient services. Specifically, we propose that payment would be made to a CMHC on an individual's behalf for partial hospitalization services or intensive outpatient services furnished by or under arrangements made by the CMHC.

Lastly, we propose to amend § 419.21(c) to refer to intensive outpatient services provided by CMHCs as services for which payment is made under the OPPS. This proposed amendment would be consistent with current regulations at § 419.21(c), which include partial hospitalization services provided by CMHCs. We note that further discussion of our proposed

payment methodology under the OPPS for intensive outpatient services is found in section VIII.D of this proposed rule.

e. Exclusion of Intensive Outpatient Services From the Outpatient Mental Health Treatment Limitation

Section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023, excludes intensive outpatient services that are not directly provided by a physician from the term ''treatment'' for the purposes of the outpatient mental health treatment limitation under section 1833(c)(1) of the Act, similar to partial hospitalization services. Accordingly, we propose to amend the regulations at § 410.155(b)(2)(iii) to state that intensive outpatient services not directly provided by a physician are not subject to the outpatient mental health treatment limitation.

3. IOP Certification and Plan of Care Requirements

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act by adding a new paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week. This certification must occur no less frequently than once every other month, and there is no requirement to certify that IOP patients would need inpatient hospitalization if they did not receive such services, which is required for PHP patients.

We propose to codify the content of the certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we propose to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for the patient to need inpatient psychiatric care if the IOP services were not provided). The physician's certification of the patient's need for either IOP or PHP services should be based on the physician's determination of the patient's needs and whether the patient meets the IOP or PHP patient eligibility criteria under § 410.44(c) or § 410.43(c), respectively. We note that the physician's certification should certify the patient's need for either IOP or PHP, and that patients participating in an IOP or PHP should not be under any other IOP or PHP plan of care for the same date of service. The patient's individualized plan of treatment should address all of the conditions that are being treated by the IOP or PHP.

Additionally, we propose to require in the regulation at § 424.24(d)(3)(ii) that the recertification of IOP services occur no less frequently than every 60 days. We believe the IOP recertification timing of no less frequently than every 60 days is consistent with the requirement in the statute that an individual be determined by a physician to have a need for IOP services ''not less frequently than once every other month'' because the minimum number of days for two consecutive months is 59 days. We believe that a consistent 60-day interval would be the most appropriate way to implement the statutory recertification requirement for IOP.

We are soliciting public comments on whether it would be appropriate to consider finalizing a shorter interval for the first recertification and for subsequent recertification for IOP patients. For example, we request comments on whether we should consider requiring an initial recertification by the 30th day of IOP services, and no less frequently than every 60 days thereafter. We request that commenters provide as much detail as possible about the rationale for a shorter recertification interval, if appropriate.

Lastly, we would make conforming changes to § 424.24(b) to add a reference to paragraph (d)(1) in the list of paragraphs that specify the content for which physician certification is required for medical and other health services furnished by providers (and not exempted under § 424.24(a)) which are paid for under Medicare Part B.

C. Coding and Billing for PHP and IOP Services Under the OPPS

We considered the similarities between the types of items and services covered by both PHP and IOP, and the larger continuum of care, when developing the proposed list of services that we believe would appropriately identify the range of services that IOPs provide to Medicare beneficiaries. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services.

Currently, hospital outpatient departments use condition code 41 to indicate that a claim is for partial hospitalization services. CMHCs do not currently use a condition code on the bill type used—that is, 76X—to indicate that a claim is for partial hospitalization services, because they are only considered a provider of services for partial hospitalization; and therefore, partial hospitalization services are identified by the 76X bill type. In order to differentiate between IOP and PHP for billing purposes, the National Uniform Billing Committee (NUBC) is has approved a new condition code, condition code 92, to identify intensive outpatient claims. Therefore, we propose to require hospitals and CMHCs to report condition code 92 on claims to indicate that a claim is for intensive outpatient services. We propose to continue to require hospitals to report condition code 41 for partial hospitalization claims. Additionally, because CMHCs would be permitted to provide both PHP and IOP beginning January 1, 2024, we also propose to require CMHCs to report condition code 41 for partial hospitalization claims. We believe that this requirement would better allow us to identify which claims are for PHP and which are for IOP. We are soliciting comment on these proposed reporting requirements for PHP and IOP.

Under current policy, PHPs submit claims with HCPCS codes to identify the services provided during each PHP day. Therefore, we worked in conjunction with physicians to develop a proposed consolidated list of all HCPCS codes that we believe would appropriately identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries. For reference, Table 42 includes the current list of HCPCS codes that are recognized for PHP payment. For CY 2024, we propose to add certain codes to the list, change the descriptions of other codes, and remove one code from the list. The list of proposed consolidated HCPCS codes is included in Table 43.

We recognize that the level of intensity of mental health services a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits would ensure a smooth transition for patients when a change in the intensity or their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as

individual mental health services. Therefore, we propose to add several HCPCS codes to the list in Table 43 that are currently recognized as mental health codes under the OPPS, but are not recognized for PHP payment.

BILLING CODE 4120–01–P

TABLE 42: CURRENT HCPCS APPLICABLE FOR PHP

HCPCS	Short Descriptor
90785	Psytx complex interactive
90791	Psych diagnostic evaluation
90792	Psych diag eval w/med srvcs
90832	Psytx pt&/family 30 minutes
90833	Psytx pt&/fam w/e&m 30 min
90834	Psytx pt&/family 45 minutes
90836	Psytx pt&/fam w/e&m 45 min
90837	Psytx pt&/family 60 minutes
90838	Psytx pt&/fam w/e&m 60 min
90845	Psychoanalysis
90846	Family psytx w/o patient
90847	Family psytx w/patient
90865	Narcosynthesis
90880	Hypnotherapy
96116	Neurobehavioral status exam
96130	Psychological testing evaluation by physician/qualified health care professional; first hour
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes
96138	Psychological/neuropsychological testing by technician; first 30 minutes
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes
96146	Psychological/neuropsychological testing; automated result only
G0129	Partial hosp prog service
G0176	Opps/php;activity therapy
G0177	Opps/php; train & educ serv
G0410	Grp psych partial hosp 45-50
G0411	Inter active grp psych parti

We propose to maintain all of the codes in Table 42, except for one code. We propose to remove 90865 Narcosynthesis, because we do not believe this code is widely used in the provision of PHP, and we do not anticipate it would be widely used in the provision of IOP in the future. We propose that the HCPCS codes listed in Table 43 would be payable when furnished by PHPs or IOPs.

TABLE 43: PROPOSED HCPCS APPLICABLE FOR PHP AND IOP

HCPCS/CPT	Short Descriptor	Proposed Action
90785	Psytx complex interactive	
90791	Psych diagnostic evaluation	
90792	Psych diag eval w/med srvcs	
90832	Psytx pt&/family 30 minutes	
90833	Psytx pt&/fam w/e&m 30 min	
90834	Psytx pt&/family 45 minutes	
90836	Psytx pt&/fam w/e&m 45 min	
90837	Psytx pt&/family 60 minutes	
90838	Psytx pt&/fam w/e&m 60 min	
90839	Psytx crisis initial 60 min	Add
90845	Psychoanalysis	
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90849	Multiple family group psytx	Add
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
90899	Psychiatric service/therapy	Add
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	
96131	Psychological testing evaluation by physician/qualified health care professional; each additional hour	
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	
96133	Neuropsychological testing evaluation by physician/qualified health care professional; each additional hour	
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	
96137	Psychological/neuropsychological testing by physician/qualified health care professional; each additional 30 minutes	
96138	Psychological/neuropsychological testing by technician; first 30 minutes	
96139	Psychological/neuropsychological testing by technician; each additional 30 minutes	
96146	Psychological/neuropsychological testing; automated result only	
96156	Hlth bhv assmt/reassessment	Add
96158	Hlth bhv ivntj indiv 1st 30	Add
96164	Hlth bhv ivntj grp 1st 30	Add
96167	Hlth bhv ivntj fam 1st 30	Add
97151	Bhv id assmt by phys/qhp	Add
97152	Bhv id suprt assmt by 1 tech	Add
97153	Adaptive behavior tx by tech	Add

HCPCS/CPT	Short Descriptor	Proposed Action
97154	Grp adapt bhv tx by tech	Add
97155	Adapt behavior tx phys/qhp	Add
97156	Fam adapt bhv tx gdn phy/qhp	Add
97157	Mult fam adapt bhv tx gdn	Add
97158	Grp adapt bhv tx by phy/qhp	Add
G0129	PHP/IOP service	Update
G0176	Opps/php/IOP; activity thrpy	Update
G0177	Opps/php/IOP; train & educ	Update
G0410	Grp psych PHP/IOP 45-50	Update
G0411	Interactive grp psyc PHP/IOP	Update
G0451	Development test interpt&rep	Add

BILLING CODE 4120–01–C

We propose to add 18 codes to the list of recognized PHP/IOP codes, as shown in Table 43. These codes are currently recognized as mental health codes under the OPPS, and we believe it would be appropriate to recognize them for PHP and IOP as well. Additionally, we propose to update the descriptions of five existing Level II HCPCS codes that are currently recognized for PHP to also refer to IOP.

As shown in Table 43, we propose to add CPT code 90853 Group psychotherapy to the list of service codes recognized for PHP and IOP. We believe there could be overlap between 90853 and two existing Level II HCPCS codes for PHP group psychotherapy, specifically G0410 and G0411. We are considering whether it would be appropriate to remove G0410 and G0411 from the list of recognized service codes for PHP and IOP, and retain only CPT code 90853. We are soliciting comments on this topic, and we are interested in hearing specific reasons commenters believe support either keeping G0410 and G0411 on the list or removing them. We are particularly interested in understanding whether it would be appropriate to maintain these codes on a temporary basis to provide a transition for existing PHPs that are using these codes.

We propose to use the list of HCPCS in Table 43 to determine the number of services per PHP or IOP day, and therefore to determine the APC per diem payment amount for each day, as discussed in section VIII.D of this proposed rule. In addition, as discussed in section VIII.D of this proposed rule, we propose to calculate the costs for 3-service and 4-service days based on the list of HCPCS in Table 43. We remind readers that currently, to qualify for payment at the applicable PHP APC (5853 or 5863) one service must be from the Partial Hospitalization Primary list. Table 44 identifies the services that are currently included in the Partial Hospitalization Primary list and those which we propose to add based on our analysis of the services included on days with three and four services from the proposed list in Table 43. We propose to maintain this requirement for CY 2024 and subsequent years to qualify for payment at the PHP or IOP APC. Thus, we propose that to qualify for payment for an IOP APC, at least one service must be from the Partial Hospitalization and Intensive Outpatient Primary list. Specifically, we propose that to qualify for payment for the IOP APC (5851, 5852, 5861 or 5862) or the PHP APC (5853, 5854, 5863, or 5864) one service must be from the Partial Hospitalization and Intensive Outpatient Primary list.

BILLING CODE 4120–01–P

TABLE 44: PROPOSED PARTIAL HOSPITALIZATION AND INTENSIVE OUTPATIENT PRIMARY SERVICES

HCPCS/CPT	Short Descriptor	Proposed Action
90832	Psytx pt&/family 30 minutes	
90834	Psytx pt&/family 45 minutes	
90837	Psytx pt&/family 60 minutes	
90845	Psychoanalysis	Add
90846	Family psytx w/o patient	
90847	Family psytx w/patient	
90853	Group psychotherapy	Add
90865	Narcosynthesis	Remove
90880	Hypnotherapy	
96112	Devel tst phys/qhp 1st hr	Add
96116	Neurobehavioral status exam	Add
96130	Psychological testing evaluation by physician/qualified health care professional; first hour	Add
96132	Neuropsychological testing evaluation by physician/qualified health care professional; first hour	Add
96136	Psychological/neuropsychological testing by physician/qualified health care professional; first 30 minutes	Add
96138	Psychological/neuropsychological testing by technician; first 30 minutes	Add
G0410	Grp psych partial hosp/IOP 45-50	Update
G0411	Inter active grp psych PHP/IOP	Update

BILLING CODE 4120–01–C

In the future, in the event there are new codes that represent the PHP and IOP services described under § 410.43(a)(4) and § 410.44(a)(4), respectively, we propose that we would add such codes to Table 43 through sub-regulatory guidance, and that these codes would be payable when furnished by a PHP or IOP. We note that coding updates frequently occur outside of the standard rulemaking timeline. We propose this sub-regulatory process in order to pay expeditiously when new codes are created that describe any of the services enumerated at § 410.43(a)(4) and § 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We would identify codes to be added sub-regulatorily if a new code is cross-walked to a previously included code, or if the code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. Any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking.

We invite public comment on the proposed consolidated list of HCPCS codes that would be payable when furnished in a PHP and IOP; and any additional codes that we should consider adding. Specifically, we are interested in hearing from commenters if there are any other existing codes that CMS should consider adding to the list, or new codes that CMS should consider creating, to describe specific services not appropriately described by the codes in Table 43. For example, we are particularly interested in and are soliciting comment on whether it would be appropriate to include caregiver-focused services in the list of recognized services for PHP and IOP. We have identified the following HCPCS codes describing services related to caregivers:

- 96202 multiple-family group behavior management/modification training for parents(s) guardians(s) caregivers(s) with a mental or physical health diagnosis, administered by a physician or other QHP without the patient present, face to face up to 60 minutes.
- 96203 each additional 15 minutes.
- 96161 administration of caregiver-focused health risk assessment instrument (that is, depression inventory) for the benefit of the patient, with scoring and documentation, per standardized instrument.
- 9X015 CAREGIVER TRAING 1ST 30 MIN
- 9X016 CAREGIVER TRAING EA ADDL 15
- 9X017 GROUP CAREGIVER TRAINING

We note that the CMHC conditions of participation at § 485.916(b) and (c) already include references to the role of

caregivers in the development and implementation of the individualized treatment plan for PHP patients, and we refer readers to section XVII.B.4 of this proposed rule for discussion of proposed amendments to the regulations at § 485.916(d). We are soliciting comments on whether it would be appropriate to include costs for such services in the calculation of PHP and IOP per diem payment rates. We note that if we were to include such services, we believe it would be appropriate to exclude them from the determination of the number of services provided per day, but we could include such services in the calculation of cost per day for determining the PHP and IOP payment rates.

Additionally, we are soliciting comments on peer services, and whether these would be appropriate to include for PHPs and IOPs. Peer support workers are people who have been successful in the recovery process who help others experiencing similar situations. Through shared understanding, respect, and mutual empowerment, peer support workers help people become and stay engaged in the recovery process and reduce the likelihood of relapse. Peer support services can effectively extend the reach of treatment beyond the clinical setting into the everyday environment of those seeking a successful, sustained recovery process. Peer support workers typically engage in a wide range of activities, including: advocating for people in recovery; sharing resources and building skills; building community and relationships; leading recovery groups; and mentoring and setting goals.[103] We are interested in information about any available codes that would appropriately describe such services.

In addition, we are soliciting comments on whether it would be appropriate to add services related to coordinating a patient's discharge from a PHP or IOP, or their transition from one level of care to another. We note that current regulations require physicians, hospitals, and CMHCs to address discharge planning for PHP patients, and we would propose the same requirements for IOP patients. Specifically, physician recertification requirements for PHP at § 424.24(e)(3)(iii)(C) state that the physician's recertification must address treatment goals for coordination of services to facilitate discharge from the partial hospitalization program. We propose the same requirement for IOP at § 424.24(d)(3)(iii)(C). Additionally, hospital CoPs at § 482.43, which apply to hospital outpatient departments providing PHP and IOP, and CMHC CoPs at § 485.914(e) require appropriate discharge planning to meet each patient's needs. We are soliciting comments on whether the codes proposed in Table 43 represent the services that PHPs and IOPs provide to support transition and discharge planning for their patients, or whether we should consider additional codes. We ask commenters to provide as much detail as possible about the nature of any additional services, and whether there are any existing codes that could describe such services.

Lastly, we note that our analysis of PHP claims showed that the provision of testing and diagnostic services is very low among PHPs, although such services are covered under the PHP benefit and we propose to include them in Table 43 and cover such services under the IOP benefit as well. We note that our analysis of non-PHP days with 3 and 4 services, which we believe could represent IOP days in the future, shows a higher provision of testing and diagnostic services than is found among PHP days. We believe that testing and diagnostic services would be included as component services of PHPs and IOPs, and we are interested in information from the public about why PHPs are not more frequently billing for these services. In particular, we welcome information from commenters about whether there are specific challenges that PHPs face in providing these services, as well as whether there are different codes, other than those proposed in Table 43 that could better describe the testing and diagnostic services that are provided to PHP patients. In addition, we are interested in understanding whether these services are typically provided by an entity other than the PHP, such as by a referring provider.

D. Proposed Payment Rate Methodology for PHP and IOP

In summary, we propose for CY 2024 to revise our methodology for calculating PHP payment rates. We propose to establish four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we propose to calculate payment rates using the broader OPPS data set, instead of hospital-based PHP data only, because we believe using the broader OPPS data set would allow CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we propose to establish consistent coding and payment between the PHP and IOP benefits, we propose to consider all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. We propose to establish four separate IOP APC per diem payment rates at the same rates we propose for PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

1. Background

The standard PHP day is typically four services or more per day. We currently provide payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient who is transitioning at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

2. Current Payment Rate Methodology for PHP

Since CY 2017, our longstanding policy has been to pay PHP on a per diem basis for days that include three or more PHP services, which are identified using a defined list of codes in the Healthcare Common Procedure Coding System (HCPCS). We currently (for CY 2023) utilize two separate PHP APC per diem payment rates: CMHC PHP APC 5853 (Partial Hospitalization (three or More Services Per Day)) using only CMHC data, and hospital-based PHP APC 8563 (Partial Hospitalization (three

[103] *https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers.*

or More Services Per Day)) using only hospital-based PHP data.

Under longstanding OPPS policy, the hospital-based PHP APC per diem payment amount is also applied as a daily mental health cap, which serves as an upper limit on payment per day for individual OPPS mental health services. Under the current methodology, for CY 2023, hospital-based PHPs are paid a per diem rate of $268.22 for three or more PHP services per day, and CMHCs are paid a per diem rate of $142.70 for three or more PHP services per day. We refer readers to the PHP ratesetting methodology described in section VIII.B.2 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70462 through 70466) for information on the current calculation of geometric mean per diem costs and payment rates for PHP APCs 5853 and 5863, and the CY 2017 OPPS/ASC final rule with comment period (81 FR 79680 through 79687) and the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 through 63666) for information on modifications incorporated into the PHP ratesetting methodology.

We note that under our current methodology, we have historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we have typically included a discussion of PHP-specific data trims, exclusions, and CCR adjustments; we are not including that discussion in this proposed rule. These PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as discussed in the following section, we propose for CY 2024 to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set. Accordingly, we propose not to apply PHP-specific trims and data exclusions, but rather to apply the same trims and data exclusions consistent with the OPPS. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this proposed rule can be found online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*).[104]

[104] Click on the link labeled ''CY 2024 OPPS/ASC Notice of Proposed Rulemaking'', which can be found under the heading ''Hospital Outpatient Prospective Payment System Rulemaking'' and open the claims accounting document link at the bottom of the page, which is labeled ''2024 NPRM OPPS Claims Accounting (PDF)''.

3. Proposed CY 2024 Payment Rate Methodology for PHP and IOP

As noted previously, the CAA, 2023 established IOP within the continuum of care, and the statute makes reference to weekly hour requirements. Specifically, IOP patients are required to be certified by a physician as needing at least 9 hours of services per week; while PHP patients are required to be certified by a physician as needing at least 20 hours of services per week.

While no IOP benefit existed prior to the CAA, 2023, we note that the types of items and services included in IOP have been, and are, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

Along with the requirements for IOP mandated by the CAA, 2023, we took into consideration information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we believe it is appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. At this time, although PHP claims can be specifically identified, there is no specific identifier or billing code to indicate IOP services. However, hospitals are permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that includes both PHP and non-PHP days with 3 or more services in order to calculate proposed payment for PHP services. In order to establish consistent payment between PHP and IOP, we propose to set IOP payment rates at the same rates as PHP. The primary goal in developing the proposed payment rate methodology for IOP and PHP services is to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years.

For CY 2024, we propose to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set, a change from the current methodology of using only PHP data. We believe using the broader OPPS data set would allow us to capture data from claims not identified as PHP, but that include the service codes and intensity required for a PHP day. The larger data set would expand the sample size to allow for more precise rate calculations. In addition, we propose to calculate the 3 services per day and 4 services per day PHP rates for CMHCs and hospital-based programs separately. We propose to set IOP payment rates for 3 services per day and 4 services per day equal to the PHP payment rates.

We also propose to set payment rates for IOP APCs at amounts equal to the payment rates for PHP APCs. We believe setting the IOP payment rates equal to the PHP payments would be appropriate because IOP is a newly established benefit, and we do not have definitive data on utilization. However, both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week. depending on the program. Therefore, we believe it is appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

For beneficiaries in a PHP or IOP, we propose applying the four-service payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with 4 or more services. For days with three or fewer services, we propose to apply the three-service payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals), which we note would be a departure from our current policy. Under our current policy, we do not make payment for any PHP days with fewer than three services, and we have heard from interested parties that this policy could discourage treatment of PHP patients when, due to extenuating circumstances, they cannot complete a full day. We believe that paying for a day with three or fewer services would allow us to more easily monitor the actual utilization of services, particularly IOP. Specifically, we believe utilizing the three-service

payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals) for days with three or fewer service would accommodate occasional instances when a patient is unable to complete a full day of PHP or IOP. We expect that days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

Additionally, we propose that the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 would also be applied as the daily mental health cap, which serves as the upper limit on payment per day for individual OPPS mental health services. We believe setting the 3 service per day hospital-based PHP APC per diem payment amount as the daily mental health cap is appropriate because currently the daily mental health cap is equal to the payment amount for hospital-based PHP APC 5863, which is payment for 3 or more services per day. Therefore, consistency with the current daily mental health cap would be maintained. Additionally, PHP is meant to be the most intensive mental health services program, requiring inpatient care if PHP is not received, and the daily mental health cap is not expected to reach such level of intensity. We believe applying the 3 service per day hospital-based PHP APC per diem payment amount for APC 5863 as the daily mental health cap would preserve the difference of intensity between PHP and individual OPPS mental health services to not incentivize one over the other. We note that the proposed CY 2024 payment amount for APC 5863 would be comparable to the CY 2023 payment amount for APC 5863, which is currently applied as the daily mental health cap.

Lastly, we note that section 4124(c) of the CAA, 2023 requires that the payment amount for intensive outpatient services furnished in FQHCs and RHCs be equal to the payment amount that would have been paid for the same service furnished by a hospital outpatient department, thus establishing site-neutral payment for hospital outpatient departments, FQHCs, and RHCs. The CAA, 2023 is silent with respect to the payment methodology for IOP services provided by CMHCs. Based on our analysis of CMHC costs, we continue to observe that CMHCs incur significantly different costs than hospitals in the provision of PHP services, and we anticipate that in the future there will be significant differences between CMHCs' and hospitals' costs of furnishing IOP services as well. We believe it is appropriate to continue to recognize the differences in cost structures for different providers of PHP. This is of particular importance not only to the Medicare program, but also for the Medicare beneficiaries that CMHCs serve, who incur a 20 percent copay on all PHP services under Part B. Therefore, we propose to continue calculating CMHC payment rates based solely on CMHC claims, but we are also considering whether establishing a site-neutral payment for all providers of IOP using data from all providers of IOP would be more appropriate in an effort to increase access to mental health services. In order to inform public awareness, we have calculated combined payment rates by using the broader OPPS data from both hospitals and CMHCs to estimate the costs associated with providing days with three and four services from the list of services in Table 43. These alternative cost calculations are found in Table 46 in section VIII.D.3.b of this proposed rule. We are soliciting comments on whether this approach would be more appropriate to consider for establishing payment beginning in CY 2024. Specifically, we are interested in any information from commenters on how IOPs may structure their service days, and how the differences in cost structures of CMHCs might affect a site-neutral payment for IOP services. We are also soliciting comments on any ways IOP days could differ from PHP days, and considerations that could affect payment. The following paragraphs describe our data analysis, and proposals for PHP and IOP APCs beginning in CY 2024.

a. Proposed PHP APC Changes and Effects on Geometric Mean Per Diem Costs

For CY 2024 and subsequent years, we propose a revision to our existing methodology to calculate the CMHC and hospital-based PHP geometric mean per diem costs to incorporate the larger data set under the OPPS, including PHP and non-PHP hospital claims for mental health services. We propose to use the latest available CY 2022 claims data, and CY 2021 cost data. This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a. of this proposed rule. In addition, we propose to establish four separate PHP APC per diem payment rates: two for CMHCs (APC 5853 and APC 5854) and two for hospital-based PHPs (APC 5863 and APC 5864). Following this proposed methodology, we propose to use the geometric mean per diem cost of $97.59 for CMHCs providing 3-service days (APC 5853), and the geometric mean per diem cost of $153.09 for CMHCs providing 4-service days (APC 5854), as the basis for developing the CY 2024 CMHC PHP APC per diem rates. Additionally, we propose to use the geometric mean per diem cost of $284.00 for hospital-based providers providing 3-service days (APC 5863), and the geometric mean per diem cost of $368.18 for hospital-based providers providing 4-service days (APC 5864) as the basis for developing the CY 2024 hospital-based PHP APC per diem rates. Lastly, we propose to establish four separate IOP APC per diem payment rates: two for CMHCs (APC 5851 and APC 5852 for 3-service days and 4-service days, respectively) and two for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively) using the same above 3-service day and 4-service day geometric mean per diem costs proposed for the PHP APC per diem rates.

b. Development of the PHP and IOP APC Geometric Mean Per Diem Costs

The types of items and services paid as PHP (and that will be paid as IOP) can also be provided outside of those benefits by hospitals; therefore, we sought to understand the costs of those services in our preliminary analysis to consider options for the proposed payment rates for IOP services. In preparation for CY 2024, in collaboration with physicians, we developed a consolidated list of all HCPCS codes that would be appropriate for identifying IOP and PHP services for analytic purposes. We refer readers to section VIII.C of this proposed rule for more detailed information on the proposed consolidated list of HCPCS codes applicable for IOP and PHP services.

We conducted a preliminary ratesetting analysis of all CMHC and hospital claims for patients that had 9 or more hours of behavioral health services per week. We then identified IOP as weeks with between 9 and 19 hours of services, and PHP as weeks with 20 hours or more of services. The relationship we observed between cost per day and cost per week suggests that typical IOP days include about three services, and typical PHP days include about four services, which as we noted previously, is also consistent with the typical service intensity for PHP.

Next, with this data set, we calculated the proposed payment rates for hospital-based providers based on costs for days with three services and days with four

services using the data from all OPPS claims for hospitals, and calculated the proposed payment rates for CMHCs based on costs for days with three services and days with four services using only the data from CMHC claims. As discussed in section VIII.B.1.a of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63666 through 63668), the costs for CMHC service days are calculated using cost report information from HCRIS. Although we anticipate that IOP weeks would generally include 9–19 hours of services and PHP weeks would generally include 20 or more hours of services, we did not restrict the data for this analysis by weekly hours. Because IOP is a new benefit, we do not have definitive data on utilization. However, if IOP utilization is similar to the data we analyzed for beneficiary weeks with 9 to 19 hours of mental health services, then we expect that IOP days will mostly include three services or fewer, but may sometimes include four or more. Given the uncertainty about how IOPs will structure their service days in the future, we believe it is appropriate to propose 3-service day and 4-service day APCs for IOP with payment rates that are the same as the rates for the 3-service day and 4-service day APCs we propose for PHP.

We analyzed all CMHC and hospital claims data under the OPPS used to set proposed rates for this CY 2024 proposed rule as described earlier in this section of this proposed rule. We identified all patient days that included three or more services from the list in Table 43. As discussed in section VIII.D.3 of this proposed rule, we propose to calculate PHP payment rates for days with three services and days with four services, and we propose to utilize these proposed PHP payment rates for the proposed IOP APCs as well. We propose to calculate separate rates for hospitals and CMHCs.

c. Proposed CY 2024 PHP and IOP APC Geometric Mean Per Diem Costs

Following this proposed structure, the calculated CY 2024 PHP geometric mean per diem cost for all CMHCs for providing 3 services per day is $97.59, which we propose to use for calculating the payment rate for the 3-service day APC, CMHC APC 5853. The calculated CY 2024 geometric mean per diem cost for all CMHCs for providing four or more services per day is $153.09, which we propose to use for calculating the payment rate for the 4-service day APC, CMHC APC 5854. As noted, the calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 3 services per service day is $284.00, which we propose to use for calculating the payment rate for the 3-service day hospital-based PHP APC 5863. The calculated CY 2024 hospital-based PHP APC geometric mean per diem cost for hospital-based PHP providers that provide 4 services per day is $368.18, which we propose to use for calculating the payment rate for the 4-service day hospital-based PHP APC 5864.

Similarly, the calculated CY 2024 IOP geometric mean per diem cost for all CMHCs for providing 3 services per day is $97.59, which we propose to use for calculating the payment rate for the 3-service day APC, CMHC APC 5851. The calculated CY 2024 geometric mean per diem cost for all CMHCs for providing 4 or more services per day is $153.09, which we propose to use for calculating the payment rate for the 4-service day APC, CMHC APC 5852. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 3 services per service day is $284.00, which we propose to use for calculating the payment rate for the 3-service day hospital-based IOP APC 5861. The calculated CY 2024 hospital-based IOP APC geometric mean per diem cost for hospital-based IOP providers that provide 4 services per day is $368.18, which we propose to use for calculating the payment rate for the 4-service day hospital-based IOP APC 5862.

We intend to monitor the provision of services in both PHP and IOP programs to better understand utilization patterns, and propose to set equal payment rates for PHP and IOP services until actual IOP utilization data becomes available for CY 2026 ratesetting, at which point we anticipate reevaluating our payment rate methodology if necessary.

In addition, we are soliciting comments on the service mix used to develop the per diem amounts for both PHP and IOP. We are interested in whether the proposed approach is appropriate, and any feedback commenters have on the service mix provided within each program.

The proposed CY 2024 PHP geometric mean per diem costs are shown in Table 45 and are used to derive the proposed CY 2024 PHP APC per diem rates for CMHCs and hospital-based PHPs. As stated in section VIII.D.3 of this proposed rule, we propose to use the same 3-service day and 4-service day geometric mean per diem PHP costs for the CY 2024 CMHC and hospital-based IOP APCs. The proposed CY 2024 PHP and IOP APC per diem rates are included in Addendum A to this proposed rule (which is available on our website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html*) and in Table 45.

TABLE 45: PROPOSED CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2024 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$97.59
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$153.09
5853	Partial Hospitalization (3 services per day) for CMHCs	$97.59
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$153.09
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$284.00
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$368.18
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$284.00
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$368.18

Alternatively, as discussed earlier in this section, we are considering establishing combined payment rates for hospitals and CMHCs based on the calculated costs per day for days with 3 services and 4 or more services, using all OPPS claims. These alternative CY 2024 PHP geometric mean per diem costs are shown in Table 46.

TABLE 46: ALTERNATIVE CY 2024 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

Group Title	Alternative PHP and IOP APC Geometric Mean Per Diem Costs
Partial Hospitalization (three services per day)	$281.48
Partial Hospitalization (four services per day)	$316.63
Intensive Outpatient (three services per day)	$281.48
Intensive Outpatient (four services per day)	$316.63

E. Proposed Outlier Policy for CMHCs

For CY 2024, we propose to update the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include intensive outpatient services. These topics are discussed in more detail. We refer readers to section II.G.1 of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 through 63470), we noted a significant difference in the amount of outlier payments made to hospitals and CMHCs for PHP services. Given the difference in PHP charges between hospitals and CMHCs, we did not believe it was appropriate to make outlier payments to CMHCs using the outlier percentage target amount and threshold established for hospitals. Therefore, beginning in CY 2004, we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs. This separate outlier threshold for CMHCs resulted in $1.8 million in outlier payments to CMHCs in CY 2004 and $0.5 million in outlier payments to CMHCs in CY 2005 (82 FR 59381). In contrast, in CY 2003, more than $30 million was paid to CMHCs in outlier payments (82 FR 59381).

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082).

We estimated CMHC per diem payments and outlier payments for this proposed rule by using the most recent available utilization and charges from CMHC claims, updated CCRs, and the proposed payment rates for PHP APCs 5853 and 5854. We recognize that

CMHCs would be permitted to provide and bill for IOP beginning in CY 2024, and would be paid under IOP APCs 5851 and 5852. However, we have not included estimates of utilization for these APCs, because the latest available claims from CY 2022 do not reflect the provision of IOP services. For increased transparency, we are providing a more detailed explanation of the existing calculation process for determining the CMHC outlier percentages. To calculate the CMHC outlier percentage, we follow three steps:

- *Step 1:* We multiply the OPPS outlier threshold, which is 1.0 percent, by the total estimated OPPS Medicare payments (before outliers) for the prospective year to calculate the estimated total OPPS outlier payments:

(0.01 × Estimated Total OPPS Payments) = Estimated Total OPPS Outlier Payments.

- *Step 2:* We estimate CMHC outlier payments by taking each provider's estimated costs (based on their allowable charges multiplied by the provider's CCR) minus each provider's estimated CMHC outlier multiplier threshold (we refer readers to section VIII.C.3 of the CY 2022 OPPS/ASC proposed rule). That threshold is determined by multiplying the provider's estimated paid days by 3.4 times the total of CMHC PHP APC and CMHC IOP payment rates. If the provider's costs exceed the threshold, we multiply that excess by 50 percent, as described in section VIII.E.3 of this proposed rule, to determine the estimated outlier payments for that provider. CMHC outlier payments are capped at 8 percent of the provider's estimated total per diem payments (including the beneficiary's copayment), as described in section VIII.E.5 of this proposed rule, so any provider's costs that exceed the CMHC outlier cap will have its payments adjusted downward. After accounting for the CMHC outlier cap, we sum all of the estimated outlier payments to determine the estimated total CMHC outlier payments.

(Each Provider's Estimated Costs—Each Provider's Estimated Multiplier Threshold) = A. If A is greater than 0, then (A × 0.50) = Estimated CMHC Outlier Payment (before cap) = B. If B is greater than (0.08 × Provider's Total Estimated Per Diem Payments), then cap adjusted B = (0.08 × Provider's Total Estimated Per Diem Payments); otherwise, B = B. Sum (B or cap- adjusted- B) for Each Provider = Total CMHC Outlier Payments.

- *Step 3:* We determine the percentage of all OPPS outlier payments that CMHCs represent by dividing the estimated CMHC outlier payments from Step 2 by the total OPPS outlier payments from Step 1:

(Estimated CMHC Outlier Payments/ Total OPPS Outlier Payments).

We propose to continue to calculate the CMHC outlier percentage according to previously established policies. However, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we propose to expand the calculation of the CMHC outlier percentage to include PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. We propose to maintain our current methodology for calculating the CMHC outlier percentage, but to apply it to payments for IOP services as well as PHP services beginning in CY 2024. Therefore, based on our CY 2024 payment estimates, including our estimates of both PHP and IOP services, CMHCs are projected to receive 0.01 percent of total hospital outpatient payments in CY 2024, excluding outlier payments. We propose to designate approximately less than 0.01 percent of the estimated 1.0 percent hospital outpatient outlier threshold for CMHCs. This percentage is based upon the formula given in Step 3.

3. Cutoff Point and Percentage Payment Amount

As described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. For example, for CY 2018, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APC 5853 exceeded 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.4 times the CY 2018 payment rate for CMHC PHP APC 5853 [0.50 × (CMHC Cost − (3.4 × APC 5853 rate))]. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 through 58997), CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 through 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004). For CY 2024, we propose to continue to pay for partial hospitalization services that exceed 3.4 times the proposed CMHC PHP APC payment rate at 50 percent of the CMHC PHP APC geometric mean per diem costs over the cutoff point. In addition, we propose to extend this policy to intensive outpatient services. That is, for CY 2024, if a CMHC's cost for partial hospitalization services paid under CMHC PHP APCs 5853 or 5854 exceeds 3.4 times the payment rate for the APC (either CMHC APC 5853 or 5854), the outlier payment would be calculated as:

[0.50 × (CMHC cost − (3.4 × (PHP APC payment)))].

Similarly, if a CMHC's cost for intensive outpatient services paid under CMHC IOP APCs 5851 or 5852 exceeds 3.4 times the payment rate for the APC (either CMHC APCs 5851 or 5852), the outlier payment would be calculated as:

[0.50 × (CMHC cost − (3.4 × (IOP APC payment)))].

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service, but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment

period (83 FR 58874 through 58875 and 81 FR 79678 through 79680).

We propose to continue these policies for partial hospitalization services provided through PHPs for CY 2024. In addition, since CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients we propose to extend these policies to include intensive outpatient services in order to encompass the full scope of services that CMHCs will be permitted to furnish. The current outlier reconciliation policy requires that providers whose outlier payments meet a specified threshold and whose overall ancillary CCRs change by plus or minus 10 percentage points or more, are subject to outlier reconciliation, pending approval of the CMS Central Office and Regional Office (as established in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68596 through 68599)). We note that the current threshold for outlier reconciliation for hospitals is $500,000, and there is no threshold for CMHCs (that is, all outlier payments are subject to reconciliation for CMHCs whose overall ancillary CCRs change by plus or minus 10 percentage points or more). The policy also includes provisions related to CCRs and to calculating the time value of money for reconciled outlier payments due to or due from Medicare, as detailed in the CY 2009 OPPS/ASC final rule with comment period and in the Medicare Claims Processing Manual (73 FR 68595 through 68599 and Medicare Claims Processing internet Only Manual, Chapter 4, Section 10.7.2 and its subsections, available at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c04.pdf*).

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated cost from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 through 79695) to limit the impact of inflated CMHC charges on outlier payments. This outlier payment cap only affects CMHCs, it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), we finalized a proposal to continue this policy in CY 2020 and subsequent years. We propose to maintain the 8 percent outlier payment cap for CY 2024 and apply it to both PHP and IOP payments. We note that the 8 percent would be calculated as 8 percent of total per diem PHP and IOP payments for CY 2024. As discussed earlier in this proposed rule, beginning in CY 2024, CMHCs will be permitted to provide and bill for intensive outpatient services for Medicare patients. Therefore, we propose to expand the calculation of the CMHC outlier cap to include both PHP and IOP, because we anticipate that total payments will increase for CMHCs in CY 2024. Therefore, we propose to calculate the 8 percent outlier payment cap for each CMHC in a way that would encompass the full scope of services that CMHCs will be permitted to furnish in CY 2024.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 through 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2023, CMHC PHP APC 5853 is the only APC for which CMHCs may receive payment under the OPPS, and is for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APC 5853, it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508), and the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004). We propose to continue this policy for CY 2024 and not set a fixed-dollar threshold for the CMHC PHP APCs (5853 or 5854) or IOP APCs (5851 or 5852).

F. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Statutory Background

The Rural Health Clinic Services Act of 1977 (Pub. L. 95–210, December 13, 1977), amended the Act by enacting section 1861(aa)(1) of the Act to extend Medicare and Medicaid entitlement and payment for primary and emergency care services furnished at a rural health clinic (RHC) by physicians and certain nonphysician practitioners, and for services and supplies incidental to their services. ''Nonphysician practitioners'' included nurse practitioners and physician assistants. (Subsequent legislation extended the definition of covered RHC services to include the services of clinical psychologists, clinical social workers, certified nurse midwives, marriage and family therapist, and mental health counselors). The statutory payment requirements for RHC services are set forth at section 1833(a)(3) of the Act, which states that RHCs are paid reasonable costs, less the amount a provider may charge as described in clause of section 1866(a)(2)(A) of the Act, but in no case may the payment exceed 80 percent of such costs.

Section 4161 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, November 5, 1990) (OBRA 90) established Federally Qualified Health Centers (FQHCs) in 1990 to be effective beginning on October 1, 1991. The law mandated that FQHCs furnish services that are typically furnished in an outpatient setting.

Section 1861(aa)(3) of the Act extends Medicare and Medicaid entitlement and payment for those services defined as RHC services under section 1861(aa)(1) of the Act, preventive services defined under section 1861(ddd)(3) of the Act, and preventive primary health services that a center is required to provide under section 330 of the Public Health Service Act furnished at a FQHC. Section 1861(aa)(4) of the Act describes the statutory requirements that FQHCs must meet to qualify for Medicare payment. Section 10501(i)(3)(A) of the

Affordable (Pub. L. 111–148) added section 1834(o) of the Act to establish a new system of payment for the costs of FQHC services under Medicare Part B (Supplemental Medical Insurance) based on prospectively set rates. Section 1834(o)(2)(A) of the Act, the FQHC prospective payment system (PPS) was effective beginning on October 1, 2014. In addition, section 10501(i)(3)(B) of the Affordable Care Act added section 1833(a)(1)(Z) to the Act to specify that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act.

Regulations pertaining to RHC and FQHC benefits are codified at 42 CFR part 405 subpart X.

b. Medicare Part B Payment of RHC and FQHC Services

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, NPs, PAs, CNMs, clinical psychologists (CPs), and clinical social workers, and under certain conditions, a registered nurse or licensed practical nurse furnishing care to a homebound RHC or FQHC patient in an area with a shortage of home health agencies. We note, effective January 1, 2024, marriage and family therapist and mental health counselor services are considered RHC services in accordance with section 1861(aa)(1)(B) of the Act as amended by section 4121(b) of CAA, 2023, which is incorporated into FQHC services through section 1861(aa)(3)(A) of the Act. In the CY 2024 PFS proposed rule, we propose to codify payment for MFTs and MHCs at § 405.2411. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

Section 130 of the Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), updated section 1833(f) of the Act by restructuring the payment limits for RHCs beginning April 1, 2021. As of April 1, 2021, all RHCs are subject to payment limits on the all-inclusive rate (AIR), and this limit will be determined for each RHC in accordance with section 1833(f) of the Act. RHCs generally are paid an AIR for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount.

FQHCs were paid under the same AIR methodology until October 1, 2014. Subsequently, FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV).

Both the RHC AIR and FQHC PPS payment rates were designed to reflect the cost of all services and supplies that an RHC or FQHC furnishes to a patient in a single day. The rates are not adjusted for the complexity of the patient health care needs, the length of the visit, or the number or type of practitioners involved in the patient's care. RHCs and FQHCs are required to file a cost report annually to determine their payment rate, which reflects adjustments for GME payments, bad debt, and influenza, pneumococcal and COVID–19 vaccines and covered monoclonal antibody products used as pre-exposure prophylaxis prevention of COVID–19 and their administration.

There are additional payments for non-face-to-face services for care management services including chronic care management (CCM), principal care management (PCM), chronic pain management (CPM), general behavior health integration (GBHI), psychiatric collaborative care model (CoCM), and virtual communications (§ 405.2464(c)).

Additionally, for FQHCs, § 405.2462(d) describes a ''grandfathered tribal FQHC'' as a FQHC that is operated by a tribe or tribal organization under the ISDEAA; was billing as if it were a provider-based to an Indian Health Service (IHS) hospital on or before April 7, 2000 and is not currently operating as a provider-based department of an IHS hospital. We refer to these tribal FQHCs as ''grandfathered tribal FQHCs'' to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000.

Under the authority in section 1834(o) of the Act to include adjustments determined appropriate by the Secretary, we revised §§ 405.2462 and 405.2464 to pay these grandfathered tribal FQHCs on the Medicare outpatient per visit rate as set annually by the IHS, and not the FQHC PPS payment rates (80 FR 71089). Such payment rates for outpatient medical care (also referred to as outpatient hospital services) furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (the PHS Act) (42 U.S.C. 248 and 249(b)) (Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, based on the previous year cost reports from Federal and tribal hospitals. The outpatient per visit rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(m), or a ''grandfathered'' tribal FQHC as described at § 405.2462(d)(1). There is a higher outpatient per visit rate for IHS and tribal Medicare visits in Alaska and a lower general outpatient per visit rate for IHS/tribal Medicare visits in the lower 48 States (IHS does not operate any hospitals or facilities in Hawaii or the territories, and thus, no rates are set in those localities). For CY 2023, the outpatient per visit rate for Medicare visits in Alaska is $801 and $620 in the lower 48 States.[105]

2. Establishment of Intensive Outpatient Services Benefit by Section 4124 of the CAA, 2023

a. Section 4124 of the Consolidated Appropriations Act of 2023

As discussed in section VIII.B.1 of this proposed rule, section 4124 of Division FF of the CAA, 2023, entitled ''Ensuring Adequate Coverage of Outpatient Mental Health Services Under the Medicare Program,'' established Medicare coverage for intensive outpatient program (IOP) services furnished by a hospital to its outpatients, or by a community mental health center (CMHC)), a FQHC or a RHC, as a distinct and organized intensive ambulatory treatment service offering less than 24-hour daily care in a location other than an individual's home or inpatient or residential setting, effective January 1, 2024.

An IOP is a distinct and organized outpatient program of psychiatric services provided for individuals who

[105] *https://www.govinfo.gov/content/pkg/FR-2023-02-27/pdf/2023-03896.pdf.*

have an acute mental illness, which includes, but is not limited to conditions such as depression, schizophrenia, and substance use disorders. Generally speaking, an IOP is thought to be less intensive than a partial hospitalization program (PHP).

This new provision mandated several changes to the RHC and FQHC policies, including scope of benefits and services, certification and plan of care requirements, and special payment rules for IOP services in RHCs and FQHCs, all of which are discussed in the paragraphs below.

3. IOP Scope of Benefits and Scope of Services in RHC and FQHC Settings

a. Background

As described in section 1861(aa) of the Act and codified under §§ 405.2411 and 405.2446, the current scope of benefits for RHC and FQHC services are those services covered in a RHC, FQHC, or other outpatient setting, including a patient's place of residence, or a Medicare-covered Part A skilled nursing facility (SNF) when provided by a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or a clinical social worker. RHC/FQHC services may also be covered for individuals who have elected hospice when provided by an RHC/FQHC physician, nurse practitioner, or physician assistant employed or under contract with the RHC or FQHC at the time the services are furnished, who has been designated by the patient as his or her attending physician. Starting January 1, 2024, services of a marriage and family therapist (MFT) or mental health counselor (MHC) are covered under RHC/FQHC services if such MFT or MHC is employed or under contract with the RHC or FQHC at the time the services are furnished.

As defined in § 405.2415, RHCs and FQHCs furnish physicians' services; services and supplies ''incident to'' the services of physicians: Nurse practitioner (NP), physician assistant (PA), certified nurse-midwife (CNM), clinical psychologist (CP), and clinical social worker (CSW) services; and services and supplies incident to the services of NPs, PAs, CNMs, CPs, and CSWs. They may also furnish diabetes self-management training and medical nutrition therapy (DSMT/MNT), transitional care management (TCM) services, and in some cases, visiting nurse services furnished by a registered professional nurse or a licensed practical nurse.

Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel (for example, nurses, medical assistants, or other clinical personnel acting under the supervision of the RHC or FQHC practitioner) are considered incident to the visit and are included in the per-visit payment.

RHC and FQHC services also include certain preventive services when specified in statute or when established through the National Coverage Determination (NCD) process. RHCs and FQHCs are paid for the professional component of allowable preventive services when all of the program requirements are met and frequency limits (where applicable) have not been exceeded.

Section 4124(b)(4) of the CAA, 2023, amended section 1861(aa)(1) of the Act by adding subparagraph (D) to establish Medicare Part B coverage for IOP services as defined in section 1861(ff)(4) of the Act when these services are furnished by RHCs, which is incorporated for FQHCs by reference in section 1861(aa)(3)(A) of the Act, effective January 1, 2024. Section 1861(ff)(2) of the Act describes the items and services available under the PHP and IOP benefits. These items and services include: individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; drugs and biologicals furnished for therapeutic purposes (which cannot, as determined in accordance with regulations, be self-administered); individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; and such other items and services as the Secretary may provide (excluding meals and transportation) that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization, and furnished pursuant to such guidelines relating to frequency and duration of services as the Secretary shall by regulation establish, taking into account accepted norms of medical practice and the reasonable expectation of patient improvement.

To be consistent with the scope of benefits required for IOP services, we propose to adopt the same standards for IOP services furnished in RHCs and FQHCs as described in section VIII.B.2 ''IOP Scope of Benefits'' of this proposed rule. Specifically, this would include individual and group therapy, occupational therapy, drugs and biologicals furnished for therapeutic purposes, which cannot be self-administered, family counseling, beneficiary education, and diagnostic services. In order to expand access to behavioral health treatment for Medicare beneficiaries and to ensure continuity of care for IOP services to best meet patient needs, we propose to make conforming regulatory changes to applicable RHC and FQHC regulations at 42 CFR part 405, subpart X, specifically,

- At § 405.2401, Scope and definitions, we propose to amend the section to add IOP services.
- At § 405.2411, Scope of benefits, we propose to amend the section to include IOP services.
- At § 405.2446, Scope of services, we propose to amend this section to include IOP services.

b. Certification and Plan of Care Requirements for IOPs in RHC and FQHC Settings

Section 4124(b)(2)(B) of the CAA, 2023 amended section 1861(ff) of the Act to add paragraph (4) to define intensive outpatient services as the items and services prescribed by a physician for an individual determined (not less frequently than once every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) (that is, an outpatient program of mostly mental health related services and therapies provided by a hospital or CMHC on an outpatient basis) under the supervision of a physician. The services must be provided pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. For patients of an IOP, section 1835(a)(2)(F)(i) of the Act does not apply, that is, individuals receiving IOP would not require

inpatient psychiatric care in the absence of such services.

In order to be consistent with physician certification and plan of care requirements required for IOP furnished in different care settings, we propose to adopt the same standards for RHCs and FQHCs providing such services as described in section VIII.B.3 ''IOP Certification and Plan of Care Requirements'' of this proposed rule. Specifically, this would require physicians to certify that an individual needs IOP services for a minimum of 9 hours per week and no more than 19 hours per week, as set out in section 4124 of CAA, 2023. This certification would require documentation to include that the individual requires such services for a minimum of 9 hours per week; require the first certification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month. Accordingly, we propose to revise our regulations at 42 CFR part 405, subpart X to specify that for the purpose of furnishing IOP services RHCs and FQHCs must similarly meet the certification and plan of care requirements at proposed § 424.24(d).

Lastly, we propose to establish the same patient eligibility criteria for intensive outpatient services as described in proposed § 410.44(c). Specifically, we propose that intensive outpatient services are intended for patients who: (1) require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care; (2) are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment; (3) do not require 24-hour care; (4) have an adequate support system while not actively engaged in the program; (5) have a mental health diagnosis; (6) are not judged to be dangerous to self or others; and (7) have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

4. Special Payment Rules for Intensive Outpatient Services

Under Medicare Part B, payment to RHCs for services (defined in § 405.2411) furnished to beneficiaries is made on the basis of an all-inclusive payment methodology subject to a maximum payment per-visit and annual reconciliation. Our regulations at § 405.2470 provide that RHCs are required to submit cost reports to allow the Medicare Administrative Contractor (MAC) to determine payment in accordance with 42 CFR part 405, subpart X, and instructions issued by CMS. The beneficiary is responsible for the Medicare Part B deductible and coinsurance amounts. Section 1866(a)(2)(A)(ii) of the Act and implementing regulations at § 405.2410(b) establish beneficiary coinsurance at an amount not to exceed 20 percent of the clinic's reasonable charges for covered services.

Under Medicare Part B, FQHCs are paid under the FQHC PPS for services (defined in § 405.2446) furnished to beneficiaries. The statutory payment requirements for FQHC services are set forth at section 1834(o) of the Act. In addition, section 1833(a)(1)(Z) to the Act requires Medicare payment for FQHC services, determined under section 1834(o) of the Act, to be 80 percent of the lesser of the actual charge or the amount determined under section 1834(o) of the Act. Under the FQHC PPS, FQHCs are paid based on the lesser of the FQHC's actual charge for the service or the PPS rate (§ 405.2462(g)(1)). The FQHC PPS rate is subsequently adjusted for certain circumstances as described under § 405.2464(b)(2). The Medicare Part B deductible does not apply to FQHC services. The beneficiary is responsible for a coinsurance amount of 20 percent of the lesser of the FQHC's actual charge for the service or the adjusted PPS rate.

As we discuss in the CY 2021 PFS final rule (85 FR 84699 through 84710), the FQHC PPS base payment is annually increased by the percentage increase in the FQHC market basket, which reflects the operating and capital cost structures for freestanding FQHC facilities. Beginning with CY 2017, FQHC PPS payments were updated using a 2013-based FQHC market basket. A complete discussion of the 2013-based FQHC market basket can be found in the CY 2017 PFS final rule (81 FR 80393 through 80403). In the CY 2021 PFS final rule, we finalized the rebasing and revising of the FQHC market basket to reflect a 2017 base year. The 2017-based FQHC market basket is primarily based on Medicare cost report data for freestanding FQHCs for 2017, which are for cost reporting periods beginning on and after October 1, 2016, and prior to September 31, 2017. We explained that we used data from cost reports beginning in FY 2017 because these data were the latest available, complete data for calculating the major cost weights for the market basket at the time of rulemaking. We also explained that CMS updates the market basket periodically so that the cost weights reflect a current mix of goods and services purchased in providing FQHC services.

Seven FQHCs that have been determined to be grandfathered tribal FQHCs and due to this designation are paid based on the lesser of the outpatient per visit rate or their actual charges, as set out at § 405.2462(f). As stated above, these grandfathered tribal FQHCs are paid the outpatient per visit rate for furnishing FQHC services.

In addition to the normal package of services, RHCs and FQHCs receive payment for certain additional services. In the CY 2022 PFS final rule (86 FR 65205 through 65206), we implemented section 132 of CAA, 2021, which amended section 1834(o) of the Act and added a new section 1834(y) to the Act, to provide statutory authority for FQHCs and RHCs, respectively, to receive payment for hospice attending physician services. In the CY 2023 PFS final rule (87 FR 69463, 69737 through 69739) we implemented sections 304(b) and (c) of division P of the CAA, 2022 (Pub. L. 117–103, March 15, 2022). Those subsections modified sections 1834(y) and 1834(o)(4) of the Act, respectively, to delay in-person visit requirements in order to for RHCs and FQHCs to receive payment for mental health visits furnished via telecommunications technology.

Section 4124(c) of the CAA, 2023 further amended section 1834(o) of the Act and section 1834(y) of the Act, to provide special payment rules for both FQHCs and RHCs, respectively, for furnishing intensive outpatient services. Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(A) to require that payment for IOP services furnished by FQHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital. In addition, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(A) to require that payment for IOP services furnished by RHCs be equal to the amount that would have been paid under Medicare for IOP services had they been covered outpatient department services furnished by a hospital.

Section VIII.D.3 of this proposed rule discusses the proposed CY 2024 payment rate methodology for IOP. We propose to establish two IOP APC per diem payment rates for hospital-based IOPs (APC 5861 and APC 5862 for 3-service days and 4-service days, respectively). We believe that it is appropriate to provide a payment structure that supports beneficiaries in an IOP where the utilization is typically structured to be days with three or fewer services. Therefore, we propose that the

rate determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs) would be the payment rate for IOP services furnished in an RHC. For IOP services furnished in FQHCs, we propose that that payment is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we propose that grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate. We propose to revise §§ 405.2410, 405.2462 and 405.2464 in the regulations to reflect the payment amount for IOP services and how the Medicare Part B deductible and coinsurance are applied.

We solicit comment on whether the payment rate for IOP services furnished in RHCs and FQHCs should be adjusted to reflect the variations in costs of furnishing services in different geographic areas and what approaches would be appropriate for determining the value of the adjustment. We also solicit comment on whether the hospital-based IOP APC 5862 for 4-service days would be appropriate for RHCs and FQHCs.

In section VIII.C of this proposed rule, we discuss coding and billing for PHP and IOP services under the OPPS. We explain that beginning January 1, 2024, the hospital outpatient department and CMHCs will be able to furnish items and services of both PHPs and IOPs. We state that we believe it is appropriate to align these programs by using a consolidated list of HCPCS codes would identify the full range of services that both IOPs and PHPs provide to Medicare beneficiaries for billing purposes. We explain that those settings paid under the OPPS and that can furnish either PHP or IOP when submitting a claim to CMS for payment would be required to report a new condition code 92 to differentiate between PHP and IOP.

While RHCs and FQHCs are not authorized to furnish PHP services, we propose to also require RHCs and FQHCs to report condition code 92 to identify intensive outpatient claims. Since RHCs and FQHCs are paid outside of the RHC AIR methodology and FQHC PPS, respectively, for IOP services we believe the condition code reporting approach would allow us to operationalize a 3 service per day payment amount using the final list of HCPCS codes used to identify the full range of services for IOP. The list of proposed HCPCS codes is included in Table 43. In addition, we propose to align with the requirement under the OPPS, which is in order to qualify for IOP payment, at least one service must be from the Intensive Outpatient Primary list. Table 44 identifies the proposed list of intensive outpatient primary services.

Section 4124(c)(1) of the CAA, 2023 amended section 1834(o) of the Act to add a new paragraph (5)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for FQHC services under the FQHC PPS. Likewise, section 4124(c)(2) of the CAA, 2023 amended section 1834(y) of the Act to add a new paragraph (3)(B) to require that costs associated with intensive outpatient services not be used to determine the amount of payment for RHC services under the methodology for all-inclusive rates (established by the Secretary) under section 1833(a)(3) of the Act. We propose conforming revisions under § 405.2468. In addition, conforming revisions will be made to the cost reporting instructions to account for these changes.

c. FQHC Supplemental Payments

As discussed in the May 2, 2014 final rule with comment period (79 FR 25461), section 1833(a)(3)(B)(i)(II) of the Act requires that FQHCs that contract with MA organizations be paid at least the same amount they would have received for the same service under the FQHC PPS. This provision ensures FQHCs are paid at least the Medicare amount for FQHC services. Therefore, if the MA organization contract rate is lower than the amount Medicare would otherwise pay for FQHC services, FQHCs that contract with MA organizations would receive a wrap-around payment from Medicare to cover the difference (see § 422.316). If the MA organization contract rate is higher than the amount Medicare would otherwise pay for FQHC services, there is no additional payment from Medicare. We believe that the special payment rule, is also included in the FQHC PPS rate as described in section 1834(o) of the Act and therefore, IOP services are included in the wrap-around payment. We propose to make revisions under § 405.2469 to reflect these changes.

5. Multiple Visits

a. Background

Currently, RHC and FQHC encounters with more than one health professional and multiple encounters with the same health professional that take place on the same day and a single location constitute a single visit, with the following exceptions:

- A patient has a medical visit and a mental health visit on the same day; or
- A patient has an initial preventive physical exam visit and a separate medical or mental health visit on the same day.

Since IOP services are behavioral health services, we do not believe it would be appropriate to pay for a mental health visit and IOP services on the same day. In the case of a medical visit, an encounter can include a medical visit and a mental health visit or a medical visit and IOP services. An encounter cannot include two mental health visits on the same day. As such, we propose to make amend § 405.2463(c) in the regulations to clarify that we will permit a mental health visit or IOP services on the same day as a medical visit.

6. Other Regulatory Updates

In addition to the regulatory changes described in this section of the rule, we propose a revision to § 405.2400 to reflect that 42 CFR part 405, subpart X is based not only on the provisions of sections 1833, 1861(aa), 1834(o) of the Act but also the provisions under section 1834(y) of the Act. We believe we inadvertently did not revise the regulations when the CAA, 2021 amended section 1834 of the Act to add new paragraph (y), as we discuss in the CY 2022 PFS final rule (86 FR 65205 through 65206).

G. Modifications Related to Medicare Coverage for Opioid Use Disorder (OUD) Treatment Services Furnished by Opioid Treatment Programs (OTPs)

1. Background

Section 2005 of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) established a new Medicare Part B benefit category for OUD treatment services furnished by OTPs during an episode of care beginning on or after January 1, 2020. In the CY 2020 Physician Fee Schedule (PFS) final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we implemented Medicare coverage and provider enrollment requirements and established a methodology for determining the bundled payments for episodes of care for the treatment of OUD furnished by OTPs. We established new codes for and finalized bundled payments for weekly episodes of care that include methadone, oral

buprenorphine, implantable buprenorphine, injectable buprenorphine or naltrexone, and non-drug episodes of care, as well as add-on codes for intake and periodic assessments, take-home dosages for methadone and oral buprenorphine, and additional counseling. For CY 2024, we propose modifications to the regulations and policies governing Medicare coverage and payment for OUD treatment services furnished by OTPs in both this proposed rule as well as the CY 2024 PFS proposed rule.

2. Statutory Authority for Coverage of Opioid Use Disorder Treatment Services Provided by OTPs

Intensive outpatient programs (IOPs) [American Society of Addiction Medicine (ASAM) Level 2.1 of Care] are diverse and flexible programs that can provide both a step-up and step-down level of care for the treatment of substance use disorders. IOPs may offer a step-down level of care in cases where a patient has been stabilized in a hospital facility or residential treatment program but continues to need services to maintain or achieve further treatment progress. IOPs also offer a step-up level of care in cases where a patient may need a higher level of care that is more structured or intensive than what can be provided in a typical outpatient treatment setting that offers care on a less frequent basis.[106] IOPs can be housed in an OTP, specialty addiction treatment facility, community mental health center (CHMC), or another setting.[107] According to the National Substance Use and Mental Health Services Survey, as of 2021, approximately 557 OTPs offer IOP services nationwide (30.1 percent of SUD treatment facilities offering OTPs).[108] Section 4124 of the CAA, 2023, which was enacted on December 29, 2022, provides for Medicare coverage and payment for IOP services in HOPDs, CMHCs, RHCs, and FQHCs. However, section 4124 of the CAA, 2023 did not address coverage for IOP services furnished in OTP settings.

Section 1861(jjj)(1) of the Act defines Opioid Use Disorder (OUD) treatment services as items and services that are furnished by an OTP for the treatment of opioid use disorder, including FDA-approved opioid agonist and antagonist medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). For matters related to payment for OUD treatment services, section 1834(w) of the Act establishes that the Secretary shall pay bundled payments to OTPs when they furnish OUD treatment services to an individual during an episode of care. Section 1834(w)(2) of the Act states that for purposes of making payments to OTPs, the Secretary may establish one or more bundles based on the type of medication provided (such as buprenorphine, methadone, naltrexone, or a new innovative drug), the frequency of services, the scope of services furnished, characteristics of the individuals furnished such services, or other factors as the Secretary determine[s] appropriate. We interpret the statutory language at sections 1861(jjj) and 1834(w) of the Act to grant the Secretary authority to establish more than one bundled payment to OTPs for OUD treatment services furnished during an episode of care provided that the scope of services is medically reasonable and necessary for the treatment of OUD. In the CY 2020 PFS final rule (84 FR 62644), we finalized a definition of OUD treatment services as those items and services that are specifically enumerated in section 1861(jjj)(1) of the Act and finalized the weekly bundled payment for an episode of care. After considering public comments, under the discretion granted to the Secretary under section 1861(jjj)(1)(F) of the Act, we also included additional items and services, including intake activities and periodic assessments within the definition of OUD treatment services specified in 42 CFR 410.67(b) (84 FR 62634). In addition, under our authority under section 1834(w) to create one or more bundled payments, we finalized that we would utilize add-on codes as a way to operationalize the creation of more than one bundled payment by making payment adjustments to the weekly bundled payment for the additional items and services.

Furthermore, CMS aims to ensure that Medicare beneficiaries have appropriate access to high quality care for the treatment of OUD, and that services provided to treat SUD under the Medicare OTP benefit are consistent with the services that are available in other settings covered under Medicare Part B. For example, when CMS first established payment policy for OTPs under Medicare Part B in the CY 2020 PFS final rule (84 FR 62630 through 62677 and 84 FR 62919 through 62926), we considered the available benefits payable under Medicare at that time in determining what items to propose to include in the bundled payment for OUD treatment services furnished by OTPs. In light of new legislation (CAA, 2023) granting authority for Medicare payment of IOP services provided by other types of health care providers, we believe it is appropriate to revisit the range of services covered under the current benefit for OUD treatment services furnished by OTPs.

In the CY 2023 PFS proposed rule, we solicited comments on whether there is a gap in coding under the PFS or other Medicare payment systems that may be limiting access to needed levels of care for treatment of mental health or substance use disorder treatment for Medicare beneficiaries (87 FR 45943 through 45944). Specifically, we sought information on multiple issues, including whether there is a gap in coding under Medicare payment systems that may be limiting access to needed levels of care for treatment of SUD; the extent to which potential gaps would best be addressed by the creation of new codes or billing rules; additional information related to IOP services, including their settings, scope and types of offered services, and practitioners involved; and, other relevant information to the extent it would inform our ability to ensure Medicare beneficiaries have access to this care. In response, many commenters noted that IOPs serve as a ''step-up'' level of care for individuals in need of more services/supports, close monitoring, and structured therapy, but who cannot stabilize at a lower level of care provided in an office setting. Commenters also noted that IOPs simultaneously serve as a ''step-down'' level of care for individuals who have more stabilized biomedical conditions and may no longer need to be hospitalized, but cannot be discharged safely. Commenters mentioned that IOPs are tailorable to patient characteristics and are often flexible in the length, frequency, and days of treatment, but that typically patients receive at least 9 hours a week of care. Moreover, commenters stated that IOPs may be provided at stand-alone IOP facilities, OTPs, partial hospitalization

[106] *https://www.ncbi.nlm.nih.gov/books/NBK64088/.*

[107] The ASAM National Guideline for the Treatment of Opioid Use Disorder (2020): *https://sitefinitystorage.blob.core.windows.net/sitefinity-production-blobs/docs/default-source/guidelines/npg-jam-supplement.pdf?sfvrsn=a00a52c2_2.*

[108] Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N–SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

programs, residential treatment centers, detoxification centers, or within a private outpatient office setting. Commenters further encouraged CMS to allow coverage for IOP services across the full continuum of care settings, so that patients can receive the care they need in the setting that is most clinically appropriate. Furthermore, several commenters emphasized the importance of ensuring access to care for IOP services provided in OTP settings. For example, one commenter recommended ''that CMS also consider whether the agency has regulatory authority to extend coverage of any new IOP billing codes to OTPs.'' Other commenters also preferred the IOP payment methodology to be amenable and complementary to the weekly bundled payment of OTPs, including a building block methodology with drug and non-drug components, and add-on codes for greater clinical complexity. As a whole, commenters were very receptive to expanding access to IOP services in multiple settings of care, including within OTPs.

Addressing the opioid crisis by expanding coverage for quality treatment options and reducing barriers to care continues to remain a high priority for CMS. Across the U.S, the rates of OUD have increased more than threefold and opioid-related mortality has increased by almost 18 percent amongst older adults in the past decade.[109] From 2015–2019, nearly 1.7 million (3 percent of all) Medicare beneficiaries had a SUD, though only 11 percent of those beneficiaries received treatment for their condition in a given year.[110] Among Medicare beneficiaries with a SUD, one-third reported that financial barriers were a reason for not receiving treatment. Research from ASPE indicates that health plans that offer coverage for a greater number of IOP services per enrollee experience higher rates of SUD treatment initiation and continued engagement within their enrollee populations.[111] This suggests that IOP services could result in an increased rate of SUD treatment initiation and continued engagement. Therefore, expanding access to IOP services in other settings and reducing financial barriers to access to IOP services through coverage could potentially increase the number of Medicare beneficiaries seeking and completing treatment for a SUD, including among Medicare beneficiaries who are members of populations that have historically been less likely to receive such treatment. Studies have shown that among individuals in need of SUD treatment, Hispanic, Black, and Asian populations are less likely to receive outpatient SUD treatment for their condition than their White counterparts, suggesting greater barriers to treatment access for these populations.[112] Other evidence indicates that Black Americans significantly underutilize specialty SUD treatment and are also less likely to complete their SUD treatment programs compared to White Americans, but these disparities are reduced when Black Americans have access to health insurance.[113] This evidence suggests that financial barriers impede initiation and completion of SUD treatment; in turn, providing health insurance coverage for SUD treatment services (such as IOP services) may lessen the impact of these financial barriers for all Medicare beneficiaries, including those who are more likely to experience these barriers. Some evidence also shows that zip codes in the U.S. within which there is at least one OTP tend to have a higher proportion of residents who are minorities (Black and Hispanic) and a lower proportion of White residents, compared to zip codes in the U.S without any OTPs,[114] and surveys of services provided by OTPs demonstrate that the majority of OTPs (82.6 percent) conduct community outreach services to those in need of treatment for OUD.[115] This suggests that OTPs may be uniquely positioned to reach minority populations in need of IOP services, which would improve their access to SUD treatment services. In addition, from 2015 to 2019 and prior to implementation of the OTP benefit, Medicare beneficiaries younger than 65 years old were more likely to receive SUD treatment than those aged 65 years old or greater, due to more beneficiaries over age 65 reporting they could not afford treatment or that the treatment was not covered by Medicare or other insurance.[116] Even after implementation of the OTP benefit, eliminating health disparities in access to SUD treatment for this older age bracket remains a priority. Therefore, we believe that expanding access to coverage and payment under Medicare for IOP services provided by OTPs may have a meaningful and positive impact on health equity, including for Medicare beneficiaries that may face barriers in accessing treatment, such as racial/ethnic minorities and/or beneficiaries aged 65 or older. Lastly, CMS' Behavioral Health Strategy includes multiple stated goals and objectives to promote person-centered behavioral health care.[117] Expanding access to coverage and payment under Medicare for IOP services provided by OTPs may help strengthen access to SUD prevention, evidence-based treatment, and recovery services, as well as advance the equity and quality of behavioral health services, which are consistent with the goals of CMS' Behavioral Health Strategy.

3. Proposal To Provide Coverage of IOP Services Furnished by OTPs

a. Proposal To Include IOP Services Furnished by OTPs in the Definition of Opioid Use Disorder Treatment Services

In recognition of the evidence provided in the discussion above, we understand that some Medicare beneficiaries may continue to face barriers in accessing treatment for their OUD. Additionally, we note that many OTPs nationwide already provide IOP services and that IOP services can be effective in promoting greater treatment initiation and engagement, which may improve health outcomes. For these reasons, and in order to expand access to behavioral health treatment for Medicare beneficiaries with OUD and ensure continuity of care between different treatment settings and levels of care, CMS is proposing to establish payment under Part B for IOP services furnished by OTPs for the treatment of OUD for CY 2024 and subsequent years.

As explained previously, section 1861(jjj)(1) of the Act defines Opioid Use Disorder (OUD) treatment services as items and services that are furnished by an OTP for the treatment of opioid use disorder, including FDA-approved opioid agonist and antagonist medications, dispensing and administration of such medications, substance use counseling, individual and group therapy, toxicology testing, and other items and services that the Secretary determines are appropriate (not including meals or transportation). IOP services are intended to treat individuals with an acute mental illness and/or substance use disorder,

[109] *https://www.sciencedirect.com/science/article/pii/S0749379721000921?via%3Dihub.*

[110] *https://doi.org/10.15585/mmwr.mm675152e1.*

[111] *https://aspe.hhs.gov/sites/default/files/private/pdf/260791/BestSUD.pdf.*

[112] *https://www.samhsa.gov/data/sites/default/files/reports/rpt35326/2021NSDUHSUChartbook102221B.pdf.*

[113] *https://www.sciencedirect.com/science/article/pii/S0376871619302443.*

[114] *https://pubmed.ncbi.nlm.nih.gov/36645315/.*

[115] *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

[116] *https://www.sciencedirect.com/science/article/pii/S0749379722001040.*

[117] *https://www.cms.gov/cms-behavioral-health-strategy.*

including those with an OUD. We believe that IOP services are similar to the specific services enumerated in section 1861(jjj)(1) of the Act, and the services and intensity of care required to provide intensive outpatient services under Level 2.1 of the ASAM continuum of care are a step-up from the services within the existing OTP benefit. The ASAM criteria's strength-based multidimensional assessment takes into account a patient's needs, obstacles and liabilities, as well as their strengths, assets, resources, and support structure; this information is used to determine the appropriate level of care across a continuum.[118] OTP services that are currently covered under the OTP benefit are at the Outpatient (Level 1) level of care, whereas IOP services are classified as Level 2.1 on ASAM's continuum of care. Individuals who meet the criteria for IOP services generally require more frequent and intensive services.

Because the Secretary has discretion under section 1861(jjj)(1)(F) of the Act to add other items and services furnished by an OTP for the treatment of OUD, as appropriate, we propose to add a new paragraph (ix) to § 410.67(b) defining a new category of services called ''OTP intensive outpatient services'' and incorporate OTP intensive outpatient services in the definition of OUD treatment services that are covered under the Part B OTP benefit. Specifically, we propose to define OTP intensive outpatient services as those services specified in proposed 42 CFR 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of Opioid Use Disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in accordance with a physician certification and plan of care. We propose that in order to qualify as ''OTP intensive outpatient services,'' a physician must certify that the individual has a need for such services for a minimum of 9 hours per week and requires a higher level of care intensity compared to existing OTP services. The specific services that we propose would be considered OTP intensive outpatient services would include any of the following:

- Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

- Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.
- Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29, excluding opioid agonist and antagonist medications that are FDA-approved for use in treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose.
- Individualized activity therapies that are not primarily recreational or diversionary.
- Family counseling, the primary purpose of which is treatment of the individual's condition.
- Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.
- Diagnostic services that are reasonable and necessary for the diagnosis or active treatment of the individual's condition, with the exception of toxicology testing.

We propose to exclude FDA-approved opioid agonist or antagonist medications for the treatment of OUD or opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, specifically, methadone, buprenorphine, naltrexone and naloxone, from the definition of OTP intensive outpatient services because these medications are already included as part of the weekly bundled payment for an episode of care or as an adjustment to the bundled payment. However, we are soliciting comment on the types of drugs and biologicals that are furnished as part of an IOP program (for example, whether IOPs furnish drugs used for emergent interventions), and the extent to which these drugs overlap with medications included in the existing weekly bundles described by HCPCS codes G2067 through G2073 and/or add-on codes described by G2078 (take-home supply of methadone), G2079 (take-home supply of oral buprenorphine), G2215 (take-home supply of nasal naloxone), G2216 (take-home supply of injectable naloxone), and G1028 (take-home supply of nasal naloxone; 2-pack of 8mg per 0.1 mL nasal spray). This information will help to inform our consideration of the extent to which the drugs and biologicals furnished as part of an IOP program would already be covered under the drug component of the weekly bundled payment and the existing add-on payments or would need to be reflected in the proposed IOP add-on payment adjustment discussed in the next section. Similarly, we propose to exclude toxicology testing from the types of diagnostic services that would be included in the definition of OTP intensive outpatient services because toxicology testing is already included within the definition of opioid use disorder treatment services and paid for as part of the weekly bundled payment for an episode of care.

b. Proposal To Establish a Weekly Payment Adjustment for IOP Services Furnished by OTPs

Section 1834(w)(2) of the Act provides discretion to implement one or more payment bundles based on the frequency, scope and characteristics of the individuals, and other factors as determined appropriate. Currently, ASAM classifies OTP services as outpatient treatment services (under Level 1 of the continuum of care), which are typically provided for less than 9 hours a week, or as a step down from intensive outpatient services, whereas intensive outpatient services (under Level 2.1 of the continuum of care) are typically provided for more than 9 hours a week and no more than 20 hours a week for adults with more severe needs than those for whom treatment provided according to Level 1 of the continuum of care is clinically appropriate.[119] In order to appropriately reflect the more intensive treatment profile for those individuals receiving IOP services versus OTP services, we propose to establish a weekly payment adjustment via an add-on code for OTP intensive outpatient services, which is consistent with the weekly bundled payment structure under the existing Medicare OTP benefit. We believe that a code billed on a weekly basis may allow greater flexibility with respect to how IOP services are rendered and how service hours may be distributed over a given week to best meet patient needs. Under this proposal, we propose that an OTP could bill for the weekly add-on code for OTP intensive services in the same week for the same beneficiary as

[118] *https://www.asam.org/asam-criteria/about-the-asam-criteria.*

[119] *https://americanaddictioncenters.org/rehab-guide/asam-criteria-levels-of-care.*

the existing coding describing a weekly OTP bundle, so long as all applicable billing requirements for each code are met. However, we note that under this proposal, each OTP intensive outpatient service must be medically reasonable and necessary and not duplicative of any service(s) for which OTPs received a bundled payments for an episode of care in a given week.

For OTP intensive outpatient services, we propose to permit OTPs to bill new HCPCS code GOTP1 (Intensive outpatient services; minimum of nine services over a 7-contiguous day period, which can include individual and group therapy with physicians or psychologists (or other mental health professionals to the extent authorized under State law); occupational therapy requiring the skills of a qualified occupational therapist; services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients; individualized activity therapies that are not primarily recreational or diversionary; family counseling (the primary purpose of which is treatment of the individual's condition); patient training and education (to the extent that training and educational activities are closely and clearly related to individual's care and treatment); diagnostic services; list separately in addition to code for primary procedure.

We propose to value HCPCS code GOTP1 based on an assumption of a typical case of three IOP services furnished per day for approximately 3 days per week. In response to the comment solicitation on IOP services in the CY 2023 PFS proposed rule, many commenters stated that a typical IOP treatment plan requires at least 9 hours of skilled treatment services per week, which would follow both the treatment protocol advised by SAMHSA and ASAM level placement criteria.[120] Moreover, the definition of intensive outpatient services in section 4124(b)(2)(B) of the CAA, 2023 specifies that in community mental health centers, hospital-based IOPs, RHCs, and FQHCs, an individual in need of IOP services must be certified by a physician to have a need for such services for a minimum of 9 hours per week compared to a minimum of 20 hours per week in a partial hospitalization service treatment program. Thus, we believe that our assumption of 9 services rendered per week would be consistent with the minimum requirement in other care settings and existing clinical guidance. Therefore, we propose to calculate the payment rate for add-on code GOTP1 based on 9 services per week. We welcome comments on whether an assumption of 9 services per week is representative of the typical number of services furnished to patients with an OUD who receive IOP services at OTPs. We propose that by billing HCPCS code GOTP1, the OTP would be attesting to the fact that it has furnished at least nine services for that week that would otherwise qualify as OTP intensive outpatient services as discussed in section VIII.G.3.a of this proposed rule. We acknowledge that not all OTP intensive outpatient services will necessarily be 60 minutes in duration, or be a time-based service, therefore, we propose that furnishing nine OTP intensive outpatient services, regardless of the length of each service, would meet the threshold to bill for HCPCS code GOTP1. We note that this aspect of our proposal differs from the proposed requirement for physician certification, discussed in section VIII.G.3.c., Certification and Plan of Care Requirements for IOPs in OTP settings, of this proposed rule, pursuant to which a physician must certify that the individual requires nine hours of OTP intensive outpatient services, and not simply nine OTP intensive outpatient services.

Under this proposal to establish a weekly add-on payment for OTP intensive outpatient services, no single service may be counted more than once for the purpose of meeting the criteria for billing for any given code. In other words, the same service could not be used to qualify to bill both the weekly bundle and the add-on payment adjustment for OTP intensive outpatient services. Additionally, we recognize that some services furnished as part of OTP intensive outpatient services may be required multiple times a week (*e.g.,* occupational therapy, patient education, family counseling, activity therapies) to meet individual patient needs and varying clinical complexity. Such services of the same type would be allowable to meet the minimum of 9 services per week, provided that all services are medically reasonable and necessary.

This proposal for the calculation of the payment rate for HCPCS code GOTP1 is similar to the payment methodology proposed for IOP services furnished in other settings. Please see a more detailed discussion regarding this payment methodology at section VIII.D ''Proposed Payment Rate Methodology for PHP and IOP'' of this proposed rule. We believe that calculating the payment rate for the proposed add-on payment adjustment for OTP intensive outpatient services based on the rate provided in a hospital setting would promote greater consistency, site neutrality, and parity with payment rates proposed for IOPs in a majority of other settings, including hospital-based IOPs, FQHCs, and RHCs.

Since IOP services have not been covered or paid under Medicare to date, CMS does not have direct data to estimate utilization and costs of IOP services. However, many of the items and services included in IOP services have been and are currently paid for by Medicare as part of the PHP benefit or under the OPPS more generally. Therefore, in our preliminary ratesetting exercise, we identified, in consultation with clinicians, a list of HCPCS codes for services that would be reasonably included as part of IOP services. Please see a more comprehensive list of these HCPCS codes used to inform the payment methodology during our preliminary ratesetting exercise in Table 43 within section VIII.C ''Coding and Billing for PHP and IOP Services under the OPPS'' of this proposed rule. The inclusion of many of these services was informed by comments we received in response to comment solicitations in the CY 2023 OPPS/ASC and PFS proposed rules. For example, some of these codes correspond to services for individual and group therapy, occupational therapy, individualized activity therapies, family counseling, and patient training and education.

For the majority of these identified HCPCS codes, the most recent utilization data available was for OPPS claims paid for dates of service in CY 2022, and the most recent cost data available was from the cost reports in CY 2021. Based on this cost and utilization data from CY 2021 and CY 2022, respectively, the estimated payment rate for 3-services per day based on APC 5861 (Intensive Outpatient (1–3 services) for Hospital-based IOPs) was $280.80; 3 services per day for 3 days a week would therefore be equal to $842.40. Because we are proposing that OTP intensive outpatient services include individual and group therapy, which are also already included in the non-drug component of the OTP bundled payments for an episode of care, we propose to subtract the amount that corresponds to the individual and group therapy proposed rate in the non-drug component of the OTP bundled payment from our estimate of $842.40 in order to establish the amount of the OTP intensive outpatient services add-on payment. Specifically, in the CY 2020 PFS final rule (84 FR 62658), we finalized a

[120] *https://www.ncbi.nlm.nih.gov/books/NBK64088/;https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.*

building block methodology to calculate the rate for the non-drug component based on established non-facility rates for similar services under the Medicare PFS, the Medicare CLFS, and state Medicaid programs. For group therapy, we used CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) as a reference code, which at the time of drafting the CY 2020 PFS final rule, in CY 2019, was assigned a non-facility rate of $27.39. In order to account for the application of the annual update to the non-drug component, the adjusted amount for group psychotherapy is currently $28.36. For individual therapy, in the CY 2023 PFS final rule (87 FR 69773), we finalized an update to the reference code used in the non-drug component to be based on the CY 2019 non-facility rate for CPT code 90834 (Psychotherapy, 45 minutes with patient), which was $91.18, and which we adjusted to account for the application of the annual update in the intervening years, resulting in $94.37. Therefore, we propose an add-on payment adjustment of approximately $719.67 for HCPCS code GOTP1 ($842.40 − ($28.36 + $94.37)). We seek comment on whether the proposed add-on payment adjustment accurately reflects the typical resource costs involved in furnishing IOP services at OTPs. We also seek comment on our proposal to adjust the proposed add-on payment adjustment to account for individual and group therapy included in the non-drug component of OTP bundled payments for an episode of care.

In accordance with the methodology used to update the payment rate for other services payable under the OTP benefit, we propose to apply an annual update based on the percentage increase in the Medicare Economic Index (MEI) to the payment rate HCPCS code GOTP1, as described in § 414.30. Additionally, consistent with the methodology used to determine payment for non-drug services furnished under the OTP benefit, we propose to apply a geographic adjustment to the payment for HCPCS code GOTP1 based on the Geographic Adjustment Factor, as described in § 414.26. Furthermore, consistent with the policy that applies for other OUD treatment services furnished by OTPs, a beneficiary copayment amount of zero would apply for OTP intensive outpatient services. Lastly, we are also seeking comment on the impact this proposal may have on dually eligible individuals, specifically, the extent to which this expanded coverage and payment may supplant Medicaid coverage for dually eligible individuals, versus the extent to which it would supplement Medicaid if it were fundamentally different from what Medicaid covers in a given state.

We recognize that in this proposed rule, we propose to adopt per diem rates for IOP services furnished in other settings, including CMHCs, hospital-based settings, FQHCs, and RHCs, and that per diem rates are used in the payment methodology for IOP services in some state Medicaid programs. Therefore, we are also seeking comment on whether a daily per diem rate based on 3 service hours per day would be more appropriate for OTP settings, especially if one payment methodology over the other would be less disruptive to OTPs as it relates to coordination of benefits. Lastly, we are seeking feedback about the experiences of furnishing IOP services within OTP settings, including the extent to which it is similar to or different than furnishing IOP services in other settings. We believe this additional information may be helpful to understand the clinical complexity of patients enrolled in OTPs who are in need of IOP services for OUD and to compare the level of care and type of services that may supplement and/or exceed those ordinarily provided under the existing OTP benefit, in order to help inform potential future rulemaking on this topic.

We propose to add a new paragraph (iv) to § 410.67(d)(4)(i)(F) in order to describe the new adjustment to the bundled payment for OTP intensive outpatient services. Additionally, we propose to amend § 410.67(d)(4)(ii) to add that the payment amounts for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26. Lastly, we propose to amend § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services will be updated annually using the Medicare Economic Index described in § 405.504(d).

c. Certification and Plan of Care Requirements for IOPs in OTP Settings

In order to be consistent with physician certification and plan of care requirements for IOP services furnished in other settings of care and to ensure, to the extent possible, that IOP services are only provided and paid for when medically necessary and appropriate for the beneficiary, we propose to adopt the same standards set forth in § 424.24(d)(1) through (3) for OTPs providing OTP intensive outpatient services (please see more detailed discussions of these proposed standards in section VIII.B.3, IOP Certification and Plan of Care Requirements, of this proposed rule. Specifically, under this proposal, a physician would be required to certify that an individual needs OTP intensive outpatient services for a minimum of 9 hours per week, which is consistent with treatment standards specified by SAMHSA and minimum hour standards described by ASAM's Level 2.1 of care for IOP services.[121] This certification would require documentation in the patient's medical record to include that the individual requires such services for a minimum of 9 hours per week; require the first recertification as of the 30th day of IOP services; and require that the certification of IOP services occur no less frequently than every other month. Accordingly, we propose to revise § 410.67(c) of our regulations to add a paragraph (5) to specify that OTPs must furnish OTP intensive outpatient services consistent with the requirements regarding content of certification, plan of treatment requirements, and recertification requirements as set forth under proposed § 424.24(d)(1) through (3).

Regarding the recertification requirements, given that OTP services are billed on a weekly basis, we propose that the required recertification could occur any time during an episode of care in which the 30th day from the start of IOP services (and every other month thereafter) falls. We note that in the CY 2020 PFS final rule (84 FR 62641), we defined an episode of care as a 1-week (contiguous 7-day) period at § 410.67(b). In the CY 2021 PFS final rule (85 FR 84691), we clarified that OTPs may choose to apply a standard billing cycle by setting a particular day of the week to begin all episodes of care, or they may choose to adopt weekly billing cycles that vary across patients, and we propose to adopt the same approach here. We welcome comments on these proposals.

We note that this proposal requires that the physician certify a need for at least 9 hours of services per week, which differs from our proposal that in order to bill for the add-on payment adjustment for OTP intensive outpatient services, the OTP must attest that it provided 9 such services to the beneficiary in a week. Given that services can vary in duration and that some services are not time-based, we believe it would be administratively simpler for OTPs to count the number of services furnished rather than to

[121] *https://www.ncbi.nlm.nih.gov/books/NBK64088/; https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.*

count the number of hours for purposes of billing the add-on payment adjustment for OTP intensive outpatient services. Additionally, as described in Section VIII.G.3.b., our proposed payment rate is based on the number of services furnished per day, rather than the number of hours, consistent with the proposals for IOP payment in other settings. In contrast, for the purposes of certification and plan of care requirements for IOPs in OTP settings, we believe that requiring a physician to certify that a beneficiary requires a minimum of 9 hours of services per week is consistent with existing clinical guidance describing the intensity of care for IOP services.[122] Additionally, a minimum of 9 hours of services per week is consistent with proposals for the certification and plan of care requirements for IOPs in other care settings. We welcome comments on both of these proposals, including whether this distinction accurately reflects the practice patterns of OTPs furnishing IOP services.

d. Correction to the OTP Regulation Text

We also propose to correct a typographical error at § 410.67(d)(3), which currently states ''At least one OUD treatment service described in paragraphs (b)(1) through (5) of this section must be furnished to bill for the bundled payment for an episode of care.'' This provision should refer to paragraphs (i) through (v) of the definition of OUD treatment service in paragraph (b). Accordingly, we propose to correct this sentence to read, ''At least one OUD treatment service described in paragraphs (i) through (v) of the definition of Opioid use disorder treatment service in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.''

H. Payment Rates Under the Medicare Physician Fee Schedule for Nonexcepted Items and Services Furnished by Nonexcepted Off-Campus Provider-Based Departments of a Hospital

1. Background

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79727) in the discussion of the proposed implementation of section 603 of the Bipartisan Budget Act (BBA) of 2015 (Pub. L. 114–74, November 2, 2015), we established the PHP payment rate under the Medicare Physician Fee Schedule (MPFS) for nonexcepted off-campus PBDs as equivalent to the level of payment made to CMHCs for furnishing three or more PHP services per day. We noted that when a beneficiary received outpatient services in an off-campus department of a hospital, the total Medicare payment for those services is generally higher than when those same services are provided in a physician's office. Similarly, when partial hospitalization services are provided in a hospital-based PHP, Medicare pays more than when those same services are provided by a CMHC. Our rationale for adopting the CMHC per diem rate for APC 5853 as the MPFS payment amount for nonexcepted PBDs providing PHP services was because CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP services as hospital-based PHPs. This is similar to the differences between freestanding entities paid under the MPFS that furnish other services also provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the MPFS, we believe CMHCs would typically have lower cost structures than hospital-based PHPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security. We explained that we believe that paying for nonexcepted hospital-based partial hospitalization services at the lower CMHC per diem rate aligns with section 603 of the BBA of 2015, while also preserving access to PHP services.

2. Proposed Payment for PHP and IOP Furnished by Nonexcepted Off-Campus Hospital Outpatient Departments

As discussed in section VIII.D of this proposed rule, we propose to change our methodology for calculating PHP payment rates by establishing separate payment rates for 3-service and 4-service days. We also propose to establish IOP payment rates for 3-service and 4-service days beginning in CY 2024. Because CMHCs have different cost structures than hospitals, we propose to establish separate CMHC and hospital rates for 3-service and 4-service PHP and IOP days. We propose to utilize the CMHC rates for PHP and IOP as the payment rates for PHP and IOP services furnished by nonexcepted off-campus hospital outpatient departments. Specifically, we propose to utilize the separate CMHC rates for 3-service and 4-service PHP days as the MPFS rates, depending upon whether a nonexcepted off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Similarly, we also propose to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

As discussed in section VIII.D of this proposed rule, we are soliciting comment on our proposed payment rates for PHP and IOP services, as well as whether commenters believe it would be appropriate to consider establishing a combined rate for 3-service days in hospitals and CMHCs, and a combined rate for 4-service days in hospitals and CMHCs. We are considering whether it would be appropriate to apply a different methodology for calculating the PHP and IOP rates for nonexcepted off-campus hospital outpatient departments and we solicit comments on alternative methodologies commenters believe would be appropriate. For example, we are considering whether it would be appropriate to apply the PFS Relativity Adjuster of 40 percent, which was established in the CY 2018 PFS rule (82 FR 53030) and which applies to most other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department. Depending on the comments we receive, we may finalize an alternative methodology such as the PFS Relativity Adjuster. We note that if we were to adopt such a methodology, we would apply it to both PHP and IOP services.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

Established in rulemaking as part of the initial implementation of the OPPS, the inpatient only (IPO) list identifies services for which Medicare will only make payment when the services are furnished in the inpatient hospital setting because of the invasive nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The IPO list was created based on the premise (rooted in the practice of medicine at that time), that Medicare should not pay for procedures furnished as outpatient services that are performed on an inpatient basis virtually all of the time for the Medicare population, for the reasons described above, because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (63 FR 47571). Services

[122] *https://www.ncbi.nlm.nih.gov/books/NBK64088/; https://store.samhsa.gov/product/TIP-47-Substance-Abuse-Clinical-Issues-in-Intensive-Outpatient-Treatment/SMA13-4182.*

included on the IPO list were those determined to require inpatient care, such as those that are highly invasive, result in major blood loss or temporary deficits of organ systems (such as neurological impairment or respiratory insufficiency), or otherwise require intensive or extensive postoperative care (65 FR 67826). There are some services designated as inpatient only that, given their clinical intensity, would not be expected to be performed in the hospital outpatient setting. For example, we have traditionally considered certain surgically invasive procedures on the brain, heart, and abdomen, such as craniotomies, coronary-artery bypass grafting, and laparotomies, to require inpatient care (65 FR 18456). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but rather means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the fact that a procedure is not on the IPO list should not be interpreted to mean the procedure is only appropriately performed in the hospital outpatient setting (70 FR 68696).

As part of the annual update process, we have historically worked with interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and to determine whether services should be added to or removed from the list. Interested parties are encouraged to request reviews for a particular code or group of codes; and we have asked that their requests include evidence that demonstrates that the procedure was performed on an outpatient basis in a safe and appropriate manner in a variety of different types of hospitals—including but not limited to—operative reports of actual cases, peer-reviewed medical literature, community medical standards and practice, physician comments, outcome data, and post-procedure care data (67 FR 66740).

We traditionally have used five longstanding criteria to determine whether a procedure should be removed from the IPO list. As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assessed whether a procedure or service met these criteria to determine whether it should be removed from the IPO list and assigned to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are the following:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be furnished in most outpatient departments.
3. The procedure is related to codes that we have already removed from the IPO list.
4. A determination is made that the procedure is being furnished in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely furnished in an ASC and is on the list of approved ASC services or has been proposed by us for addition to the ASC covered procedures list.

In the past, we have requested that interested parties submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and was safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols. Our clinicians then thoroughly review all information submitted within the context of the established criteria and if, following this review, we determine that there is sufficient evidence to confirm that the code could be safely and appropriately performed on an outpatient basis, we assign the service to an APC and include it as a payable procedure under the OPPS (67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and review the Medicare Severity Diagnosis Related Groups (MS–DRG) rate for the service under the IPPS, though we note we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting.

We stated in prior rulemaking that, over time, given advances in technology and surgical technique, we would continue to evaluate services to determine whether they should be removed from the IPO list. Our goal is to ensure that inpatient only designations are consistent with the current standards of practice. We have asserted in prior rulemaking that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we would be prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443). Further, CMS has at times had to reclassify codes as inpatient only services with the emergence of new information.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74352 through 74353) for a full discussion of our historic policies for identifying services that are typically provided only in an inpatient setting and that, therefore, will not be paid by Medicare under the OPPS, as well as the criteria we have used to review the IPO list to determine whether any services should be removed.

B. Changes to the Inpatient Only (IPO) List

As stated above, we encourage interested parties to request reviews for a particular code or group of codes for removal from the IPO list. For CY 2024, we received several requests from interested parties recommending particular services to be removed from the IPO list. Following our clinical review, we did not find sufficient evidence that, using the five criteria listed above, these services meet the criteria to be removed from the IPO list for CY 2024. Therefore, we are not proposing to remove any services from the IPO list for CY 2024.

We propose to add nine services for which codes were newly created by the AMA CPT Editorial Panel for CY 2024 to the IPO list. These new services are described by the placeholder CPT codes X114T, 2X002, 2X003, 2X004, 619X1, 7X000, 7X001, 7X002, and 7X003, which will be effective on January 1, 2024. After clinical review of these services, we found that they require a hospital inpatient admission or stay and thus, we believe they are not appropriate for payment under the OPPS. We propose to assign these services to status indicator ''C'' (Inpatient Only) for CY 2024. Additionally, we propose to reassign CPT code 0646T from status indicator ''E1'' (not payable by Medicare) to ''C,'' effective CY 2024. The CPT codes, long descriptors, and the proposed CY 2024 payment indicators are displayed in Table 47.

Table 47 below contains the proposed changes to the IPO list for CY 2024. The

complete list of codes describing services that are proposed to be designated as inpatient only services beginning in CY 2024 is also included as Addendum E to this proposed rule, which is available via the internet on the CMS website.

BILLING CODE 4120–01–P

TABLE 47: PROPOSED CHANGES TO THE INPATIENT ONLY (IPO) LIST FOR CY 2024

CY 2024 CPT Code	CY 2024 Long Descriptor	Action	CY 2024 Proposed Status Indicator
X114T	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
2X002	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	Add to the IPO list	C
2X003	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	Add to the IPO list	C
2X004	Revision (e.g., augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	Add to the IPO list	C
619X1	Insertion of skull-mounted cranial neurostimulator pulse generator or receiver, including craniectomy or craniotomy, when performed, with direct or inductive coupling, with connection to depth and/or cortical strip electrode array(s)	Add to the IPO list	C
7X000	Ultrasound, intraoperative thoracic aorta (e.g., epiaortic), diagnostic	Add to the IPO list	C
7X001	Intraoperative epicardial cardiac (e.g., echocardiography) ultrasound for congenital heart disease, diagnostic; including placement and manipulation of transducer, image acquisition, interpretation and report	Add to the IPO list	C
7X002	placement, manipulation of transducer, and image acquisition only	Add to the IPO list	C
7X003	interpretation and report only	Add to the IPO list	C
0646T	Transcatheter tricuspid valve implantation (ttvi)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	Add to the IPO list	C

BILLING CODE 4120–01–C

C. Solicitation of Public Comments on the Services Described by CPT Codes 43775, 43644, 43645, and 44204

We are soliciting comments regarding whether the services described by CPT codes 43775 (Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (*i.e.,* sleeve gastrectomy)), 43644 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and roux-en-y gastroenterostomy (roux limb 150 cm or less)), 43645 (Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and small intestine reconstruction to limit absorption), and 44204 (Laparoscopy, surgical; colectomy, partial, with anastomosis) are appropriate to be removed from the IPO list. At this time, we do not believe that we have adequate information to determine whether the services described by CPT codes 43775, 43644, 43645, and 44204 can be safely performed in the hospital outpatient department setting on the Medicare population. Therefore, we are specifically requesting information on evidence that these services can be performed safely on the Medicare population in the outpatient setting. We are also seeking public comments on whether the services described by CPT codes 43775, 43644, 43645, and 44204 specifically meet any of the five criteria to be removed from the IPO list mentioned above.

X. Proposed Nonrecurring Policy Changes

A. Supervision by Nurse Practitioners, Physician Assistants, and Clinical Nurse Specialists of Cardiac Rehabilitation, Intensive Cardiac Rehabilitation, and Pulmonary Rehabilitation Services Furnished to Hospital Outpatients

1. Background

Section 51008(a) of the Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123) amended section 1861(eee)(1) and (2) of the Act to revise the definitions of cardiac rehabilitation (CR) program and intensive cardiac rehabilitation (ICR) program, respectively, to provide that services these programs furnish can be under the supervision of a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS). Section 51008(b) of the BBA of 2018 amended section 1861(fff)(1) of the Act similarly to revise the definition of a pulmonary rehabilitation (PR) program to provide that PR services can be furnished under the supervision of these same types of practitioners. Section 51008(c) of the BBA of 2018 provides that these amendments apply to items and services furnished on or after January 1, 2024. Before the effective date of these amendments, only physicians could supervise services furnished as part of CR, ICR, and PR programs.

To implement these amendments, we propose in the CY 2024 PFS proposed rule to revise the regulations at 42 CFR 410.47 and 410.49, which describe the conditions of coverage for the CR, ICR and PR programs, to provide that physician assistants, nurse practitioners, and clinical nurse specialists can supervise CR, ICR and PR program services. Specifically, the CY 2024 PFS proposed rule proposes to amend §§ 410.47 and 410.49 to provide that supervision of pulmonary rehabilitation, cardiac rehabilitation and intensive cardiac rehabilitation services can be provided by a physician, PA, NP, or CNS.

2. Proposed Conforming Revisions to § 410.27

Correspondingly, to implement the amendments to section 1861(eee)(1) and (2) and (fff) of the Act, and to be consistent with the proposed revisions to § 410.47 and § 410.49, we propose to make conforming revisions to § 410.27, which describes the conditions for coverage for therapeutic outpatient hospital or CAH services and supplies provided incident to a physician's or nonphysician practitioner's service.

Currently, § 410.27(a)(1)(iv)(B)(1) provides that for PR, CR, and ICR services, direct supervision must be furnished by a doctor of medicine or osteopathy as specified in §§ 410.47 and 410.49. We propose to delete the reference to a doctor of medicine or osteopathy and retain the cross-reference to §§ 410.47 and 410.49. As the text remaining following this deletion would consist solely of cross-references to the newly revised §§ 410.47 and 410.49, this would have the effect of expanding who may provide supervision for CR, ICR and PR to include PAs, NPs, and CNSs for purposes of supervision of PR, CR, and ICR services under § 410.27.

In the interim final rule with comment period titled ''Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency,'' published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D) to provide that, during a Public Health Emergency as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for PR, CR, and ICR services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(D) in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

In the CY 2022 PFS final rule, CMS added CPT codes 93797 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)) and 93798 (Physician or other qualified health care professional services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)) and HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ecg monitoring; without exercise, per session) to the Medicare Telehealth Services List on a Category 3 basis (86 FR 65055).

In order to effectuate a similar policy under the OPPS, where PR, CR, and ICR rehabilitation services could be furnished during the PHE to beneficiaries in hospitals under direct supervision of a physician where the supervising practitioner is immediately available to be present via two-way, audio/video communications technology, in the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision to include the presence of the supervising practitioner through two-way, audio/video telecommunications technology until December 31, 2023 (87 FR 72019 through 72020). Under the telehealth flexibilities extended in the CAA, 2023, these services will remain on the Medicare Telehealth Services List through the end of CY 2024. In the interest of maintaining similar policies for direct supervision of PR, CR, and

ICR under the OPPS and PFS, we propose to further revise § 410.27(a)(1)(iv)(B)(1) to allow for the direct supervision requirement for CR, ICR, and PR to include virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who are eligible to supervise these services in CY 2024. We are also soliciting comments on whether there are safety and/or quality of care concerns regarding adopting this policy beyond the current or proposed extensions and what policies CMS could adopt to address those concerns if the policy were extended beyond 2023.

For the complete discussion of the proposed revisions to § 410.47 and § 410.49, we refer readers to the CY 2024 PFS proposed rule that is published elsewhere in the **Federal Register**.

B. Payment for Intensive Cardiac Rehabilitation Services (ICR) Provided by an Off-Campus, Non-Excepted Provider Based Department (PBD) of a Hospital

1. Background on Intensive Cardiac Rehabilitation

Section 144(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275) made a number of changes to the Act related to coverage and payment for pulmonary and cardiac rehabilitation services furnished to beneficiaries with chronic obstructive pulmonary disease and certain other conditions, effective January 1, 2010. Specifically, section 144(a)(1)(A) of MIPPA amended section 1861(s)(2) of the Act by adding new subparagraphs (CC) and (DD) to provide for Medicare Part B coverage of items and services furnished under a cardiac rehabilitation (CR) program (as defined in a new section 1861(eee)(1) of the Act); a pulmonary rehabilitation (PR) program (as defined in a new section 1861(fff)(1) of the Act); and an intensive cardiac rehabilitation (ICR) program (as defined in a new section 1861(eee)(4) of the Act). The amendments made by section 144(a) of MIPPA provide for coverage of CR, PR, and ICR program services provided in a physician's office, in a hospital on an outpatient basis, and in other settings determined appropriate by the Secretary.

Section 144(a)(2) of MIPPA amended section 1848(j)(3) of the Act to provide for payment for services furnished in an ICR program under the PFS and also added a new paragraph (5) to section 1848(b) of the Act. Section 1848(b)(5)(A) requires the Secretary for ICR program services to substitute the Medicare OPD fee schedule amount established under the OPPS for cardiac rehabilitation (under HCPCS codes 93797 and 93798 for calendar year 2007, or any succeeding HCPCS codes for cardiac rehabilitation). For a full discussion of implementation of the MIPPA amendments related to coverage and payment for PR, CR, and ICR programs under the OPPS, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60566 through 60574).

2. Background on Section 603 of the Bipartisan Budget Act of 2015 and the PFS Relativity Adjuster

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114–74) (BBA, 2015) (hereinafter referred to as ''section 603'') amended section 1833(t) of the Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS and are instead paid ''under the applicable payment system'' under Medicare Part B if the requirements for such payment are otherwise met. Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of ''covered OPD services'' applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719), we adopted a number of policies to implement section 603. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made under the applicable payment system designated under section 1833(t)(21)(C) of the Act; (2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and (3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

To effectuate payment for nonexcepted items and services, in the CY 2017 interim final rule with comment period (81 FR 79720 through 79729), we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS Relativity Adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate) (82 FR 53030).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier ''PN'' to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim utilizing modifier ''PN'' to indicate that an item or service is a nonexcepted item or service.

For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720

through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

3. Proposal To Modify Claims Processing of HCPCs Codes G0422 and G0423 To Address an Unintended Payment Disparity Caused by Application of the PFS Relativity Adjuster to ICR Services Furnished by Off-Campus Non-Excepted PBDs Hospitals

Since 2010, ICR services provided in the physician's office have been paid at 100 percent of the OPPS rate for CR services as required by 1848(b)(5). Since 2017, ICR services provided by an off-campus, non-excepted PBD of a hospital have been paid at the above-described ''PFS-equivalent'' rate through application of the PFS Relativity Adjuster, which was 50 percent of the OPPS rate in CY 2017 and 40 percent of the OPPS rate in CY 2018 and thereafter, consistent with the above-described implementation of section 603.

This has produced an outcome inconsistent with the text of section 1848(a)(5)(A) and at odds with the intent of section 603, which was to remove the significant disparity in payment rates for the same services depending on whether they were furnished in a physician's office or an off-campus, non-excepted PBD of a hospital. When the PFS Relativity Adjuster was implemented in 2017, payment for the ICR service provided in a physician's office and a PBD of an off-campus, non-excepted hospital was already the same pursuant to section 1848(b)(5)(A), which explicitly requires ICR services provided in a physician's office to be paid at the OPPS rate for cardiac rehabilitation. Consequently, application of the 40 percent PFS Relativity Adjuster to payment for ICR provided by an off-campus, non-excepted PBD has resulted in an unintended reimbursement disparity between the two sites of the service, as shown in Table 48.

TABLE 48: 2023 REIMBURSEMENT FOR HCPCS CODES G0422 AND G0423 UNDER THE OPPS ON-CAMPUS RATE, OPPS NON-EXCEPTED RATE AND PFS RATE

HCPCS Code	2023 OPPS On-Campus Rate	2023 OPPS Non-Excepted Rate	2023 Medicare PFS Payment Rate
G0422 (intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session)	$120.47	$48.03	$120.47
G0423 (intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session)	$120.47	$48.03	$120.47

This disparity creates a significant barrier to beneficiary access to an already underutilized service. To eliminate this unintended outcome and for consistency with the requirement in section 1848(b)(5)(A) of the Act to substitute the OPPS rate for CR services for the PFS rate for ICR services, we propose to pay for ICR services provided by an off-campus, non-excepted provider-based department of a hospital at 100 percent of the OPPS rate for CR services (which is also 100 percent of the PFS rate) rather than at 40 percent of the OPPS rate. Effective January 1, 2024, we propose to exclude ICR from the 40 percent Relativity Adjuster policy at the code level by modifying the claims processing of HCPCS codes G0422 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring with exercise, per session) and G0423 (Intensive cardiac rehabilitation; with or without continuous ECG monitoring without exercise, per session) so that 100 percent of the OPPS rate for CR is paid irrespective of the presence of the ''PN'' modifier (signifying a service provided in a non-excepted off-campus provider-based department of a hospital) on the claim. We solicit comment on whether there are other services for which the OPPS rate is unconditionally used under the PFS, such that these services should be treated similarly for purposes of payment to off-campus, non-excepted provider-based departments of hospitals.

C. OPPS Payment for Specimen Collection for COVID–19 Tests

In the May 8th, 2020 COVID–19 interim final rule with comment period titled ''Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program'', we created a new E/M code to support COVID–19 testing during the PHE: HCPCS code C9803 (Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars–cov–2) (coronavirus disease [covid–19]), any specimen source) (85 FR 27604). In our review of available HCPCS and CPT codes for the May 8th, 2020 COVID–19 IFC, we did not identify a prior code that explicitly described the exact services of symptom assessment and specimen collection that HOPDs were undertaking to facilitate widespread testing for COVID–19. We believed that HCPCS code C9803 was necessary to meet the resource requirements for HOPDs to provide extensive testing for the duration of the COVID–19 PHE. This code was created only to meet the need of the COVID–19 PHE and we stated that we expected to retire this code at the conclusion of the COVID–19 PHE (85 FR 27604).

We assigned HCPCS code C9803 to APC 5731—Level 1 Minor Procedures effective March 1, 2020 for the duration of the COVID–19 PHE. In accordance with Section 1833(t)(2)(B) of the Act, APC 5731—Level 1 Minor Procedures contains services similar to HCPCS code C9803. APC 5731—Level 1 Minor Procedures has a payment rate of $24.96 for CY 2023. HCPCS code C9803 was

also assigned a status indicator of ''Q1.'' The Q1 status indicator indicates that the OPPS will package services billed under HCPCS code C9803 when billed with a separately payable primary service in the same encounter. When HCPCS code C9803 is billed without another separately payable primary service, we explained that we will make separate payment for the service under the OPPS. The OPPS also makes separate payment for HCPCS code C9803 when it is billed with a clinical diagnostic laboratory test with a status indicator of ''A'' on Addendum B of the OPPS. On May 11, 2023, the COVID–19 PHE concluded.[123] As stated above, we created HCPCS code C9803 to meet the need of the COVID–19 PHE and the resource requirements for HOPDs during the PHE, and planned to retire the code following the conclusion of the PHE. While the code will remain active for the remainder of CY 2023 for technical reasons, we do not believe it is necessary for the code remain active in CY 2024 now that the PHE has concluded. Therefore, we propose to delete HCPCS code C9803 effective January 1, 2024. We solicit comment on our proposal to delete this code for CY 2024.

D. Remote Services

1. Mental Health Services Furnished Remotely by Hospital Staff to Beneficiaries in Their Homes

In the CY 2023 OPPS final rule with comment period (87 FR 72012 through 72017), we finalized creation of three HCPCS C-codes to describe mental health services furnished by hospital staff to beneficiaries in their homes through communications technology. See Table 49 for the C-code numbers and their descriptors.

BILLING CODE 4120–01–P

TABLE 49: C-CODE NUMBERS AND LONG DESCRIPTORS

HCPCS Code	Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, initial 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to code for primary service)

When we created HCPCS codes C7900 through C7902, we did not specify whether they should be used for individual or group services, preferring to keep the coding more general while we gathered information about the use of these new codes. However, we have heard from interested parties that, in instances when a beneficiary is receiving multiple units of group therapy a day, it is administratively burdensome to report and document each unit of time using multiple codes. Instead, interested parties requested that we create a single, untimed code that can be reported when a beneficiary receives multiple hours of group therapy per day. In order to reduce administrative burden and enhance access to these services, we propose to create a new, untimed, HCPCS C-code describing group therapy. Please see Table 50 for the proposed C-code and long descriptor.

TABLE 50: PROPOSED C-CODE NUMBER AND LONG DESCRIPTOR

HCPCS	Long Descriptor
C79XX	Group psychotherapy service for diagnosis, evaluation, or treatment of a mental health or substance use disorder provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service

[123] *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

As we stated in the CY 2023 OPPS final rule with comment period, when beneficiaries are in their homes and not physically within the hospital, the hospital is not accruing all the costs associated with an in-person service; and the full OPPS rate would not accurately reflect these reduced costs. We believe that the costs associated with hospital clinical staff remotely furnishing a mental health service to a beneficiary who is in their home using communications technology more closely resembles the PFS payment amount for similar services when performed in a facility, which reflects the time and intensity of the professional work associated with performing the mental health service but does not reflect certain practice expense costs, such as clinical labor, equipment, or supplies (87 FR 72015).

In keeping with that methodology, we propose to assign HCPCS code C79XX to an APC based on the facility payment amount for a clinically similar service, CPT code 90853 (Group psychotherapy (other than of a multiple-family group)) under the PFS. See Table 51 for the proposed SI and APC assignments and payment rates for HCPCS code C79XX.

TABLE 51: PROPOSED CY 2023 SI, APC ASSIGNMENT, AND GEOMETRIC MEAN COST FOR HCPCS CODE C97XX

HCPCS	Short Descriptor	Proposed SI	Proposed Proxy Service	PFS Facility Rate	Proposed APC	APC GMC
C79XX	HOPD mntl hlt, grp	S	90853	$23.38	5821	$28.62

We seek comment on whether HCPCS code C79XX sufficiently describes group psychotherapy to the extent that group psychotherapy would no longer be reported with HCPCS codes C7900–C7902, in which case we would need to refine the code descriptors for HCPCS codes C7900–C7902 to stipulate that they are solely for services furnished to an individual beneficiary. Alternatively, we are seeking comment on whether or there are circumstances where interested parties believe it would be appropriate to bill for group services using HCPCS codes C7900–C7902. We also seek comment on any further refinements to the code descriptors, valuation, or billing guidance.

We have also heard from interested parties that there is confusion about the presence of the word ''initial'' in the descriptors for HCPCS codes C7900 and C7901 and that this is preventing billing for remote behavioral health services furnished subsequent to either the first 15 to 29 minutes or 30 to 60 minutes. In order to facilitate accurate billing, regardless of whether the remote mental health service is being furnished as an initial or subsequent service, we propose to revise the code descriptors to remove the word ''initial.'' We also propose to revise the descriptor for HCPCS code C7902 to limit billing with HCPCS code C7901. See Table 52 for revised code descriptors.

TABLE 52: PROPOSED DESCRIPTORS FOR HCPCS CODES C9700 AND C9701

HCPCS	Proposed Long Descriptor
C7900	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 15-29 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7901	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, 30-60 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service
C7902	Service for diagnosis, evaluation, or treatment of a mental health or substance use disorder, each additional 15 minutes, provided remotely by hospital staff who are licensed to provide mental health services under applicable State law(s), when the patient is in their home, and there is no associated professional service (List separately in addition to HCPCS code C9701)

BILLING CODE 4120–01–C

2. Periodic In-Person Visits

In the CY 2023 OPPS final rule with comment period (87 FR 72017), we finalized a requirement that payment for mental health services furnished remotely to beneficiaries in their homes using telecommunications technology may only be made if the beneficiary receives an in-person service within 6 months prior to the first time the hospital clinical staff provides the mental health services remotely; and that there must be an in-person service without the use of telecommunications technology within 12 months of each mental health service furnished remotely by the hospital clinical staff. We also finalized that we would permit exceptions to the requirement that there be an in-person service without the use of communications technology within 12 months of each remotely furnished mental health service when the hospital clinical staff member and beneficiary agree that the risks and burdens of an in-person service outweigh the benefits

of it. We stated that exceptions to the in-person visit requirement should involve a clear justification documented in the beneficiary's medical record including the clinician's professional judgement that the patient is clinically stable and/or that an in-person visit has the risk of worsening the person's condition, creating undue hardship on the person or their family, or would otherwise result in disengaging with care that has been effective in managing the person's illness. We also finalized that hospitals must document that the patient has a regular source of general medical care and has the ability to obtain any needed point of care testing, including vital sign monitoring and laboratory studies. We finalized that these requirements would not go into effect until the 152nd day after the PHE for COVID–19 ends to maintain consistency with similar policies implemented for professional services paid under the PFS, and for RHCs/FQHCs (87 FR 72018).

Section 4113(d) of the Consolidated Appropriations Act (CAA), 2023, (Pub. L. 117–328) extended the delay in implementing the in-person visit requirements until January 1, 2025, for both professionals billing for mental health services via Medicare telehealth and for RHCs/FQHCs furnishing remote mental health visits. As previously stated, we believe it is important to maintain consistent requirements for these policies across payment systems; therefore we propose to delay the in-person visit requirements for mental health services furnished remotely by hospital staff to beneficiaries in their homes until January 1, 2025.

3. Payment for Outpatient Therapy Services, Diabetes Self-Management Training, and Medical Nutrition Therapy When Furnished by Hospital Staff to Beneficiaries in Their Homes Through Communication Technology

The CAA, 2023 extended most flexibilities for Medicare telehealth services, including retention of physical and occupational therapists and speech-language pathologists as telehealth distant site practitioners, through the end of CY 2024. In the CY 2024 PFS proposed rule, we propose to continue to make payment for outpatient therapy (physical therapy, occupational therapy, and speech-language pathology) services, Diabetes Self-Management Training, and Medical Nutrition Therapy when furnished via telehealth by qualified employed staff of institutional providers through the end of CY 2024. We note that this proposal includes outpatient therapy, DSMT, and MNT services furnished via telehealth by staff of hospital outpatient departments. For further discussion, please see the CY 2024 PFS proposed rule.

E. OPPS Payment for Dental Services

Background

Section 1862(a)(12) of the Act generally precludes payment under Medicare Parts A or B for any expenses incurred for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth. (Collectively here, we will refer to ''the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth'' as ''dental services.'') In the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 69663), we explained that we believe there are instances where dental services are so integral to other medically necessary services that they are not in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to the clinical success of an otherwise covered medical service, and therefore, are instead substantially related and integral to that primary medical service. To provide greater clarity to our current policies and respond to issues raised by interested parties, in the CY 2023 PFS final rule, we finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to, and substantially related and integral to the clinical success of, other covered medical services (hereafter in this discussion, ''inextricably linked to other covered services''); (2) clarification and codification of certain longstanding Medicare FFS payment policies for inextricably linked dental services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; (4) for CY 2024, that Medicare Part A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers; and (5) beginning for CY 2023, the establishment of a process to submit for our consideration and review additional dental services that are inextricably linked to other covered medical services (87 FR 69670 through 69671). The CY 2023 PFS final rule specified that Medicare payment for these dental services may be made regardless of whether the services are furnished in an inpatient or outpatient setting. We direct readers to the CY 2023 PFS final rule (87 FR 69663 through 69688) for a full discussion of these policies as well as to the CY 2024 PFS proposed rule for proposals related to dental services.

In the CY 2023 PFS final rule, CMS identified various examples of HCPCS codes, mostly Current Dental Terminology (CDT®) codes, that could be used to describe the types of dental services identified in the CY 2023 PFS final rule for which Medicare payment can be made when coverage and payment policy requirements are met (87 FR 69667). We refer readers to the PFS Relative Value Files that are released quarterly on the CMS website for a comprehensive list of HCPCS codes, including D-codes, that may be payable under the PFS, available at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/physicianfeesched/pfs-relative-value-files*.

The policies adopted in the CY 2023 PFS final rule allow payment for certain dental services performed in outpatient settings. However, the current dental codes assigned to APCs for CY 2023 do not fully describe the dental services that may be inextricably linked to covered medical services and payable under Medicare Part B. Specifically, for the OPPS for CY 2023, only 57 CDT codes are assigned to APCs and payable under the OPPS when coverage and payment conditions are met. In addition to the small number of CDT codes assigned to APCs for CY 2023, there is also a limited number of CPT codes that may describe dental services, including CPT code 41899 (Unlisted px dentalvlr strux), that are currently assigned to APCs and payable under the OPPS.

In the CY 2023 OPPS/ASC final rule with comment period, we created HCPCS code G0330 to describe facility services for dental rehabilitation procedure(s) furnished to patients who require monitored anesthesia (*e.g.,* general, intravenous sedation (monitored anesthesia care)) and use of an operating room. We finalized this code based on extensive public comments expressing the need for a coding and payment mechanism to improve access to covered dental procedures under anesthesia, especially dental rehabilitation procedures, an issue that commenters to the CY 2023 OPPS proposed rule explained is caused by barriers to securing sufficient operating room time to furnish these services. We further noted that HCPCS code G0330 must only be used to describe facility fees for dental

rehabilitation services that meet Medicare payment and coverage requirements as interpreted in the CY 2023 PFS final rule. We explained that HCPCS code G0330 cannot be used to describe or bill the facility fee for noncovered dental professional services. We assigned HCPCS code G0330 to APC 5871 (Dental Procedures) for CY 2023. We direct readers to the CY 2023 OPPS/ASC final rule with comment period for a full discussion on HCPCS code G0330 (87 FR 71882 through 71883). For CY 2024, we do not propose to change the APC assignment for HCPCS code G0330. However, we refer readers to the section XIII of this proposed rule for a proposal regarding payment for HCPCS code G0330 under the ASC payment system.

2. Proposed OPPS Payment for Additional Dental Codes Beginning in CY 2024

To ensure that dental services can be paid under the OPPS when consistent with the policies and clarifications included in the CY 2023 PFS final rule, we propose to assign additional dental codes to APCs for CY 2024. Specifically, for CY 2024, we propose to assign 229 additional dental codes to clinical APCs to enable them to be paid for under the OPPS when payment and coverage requirements are met. Assigning additional dental codes to clinical APCs would result in greater consistency in Medicare payment for different sites of service and help ensure patient access to dental services for which payment can be made when performed in the hospital outpatient setting.

Prior to detailing our proposals, we note two things for readers' awareness. First, OPPS payment will only be made for a dental code that we propose to assign to an APC for CY 2024 if it is among the types of dental services for which payment can be made as described in the regulation at § 411.15(i)(3)(i). As we have consistently stated in past rules (87 FR 71879) and quarterly change requests to assign new codes to APCs (see, *e.g.,* Pub 100–04 Medicare Claims Processing, Transmittal 11937), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program. Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Accordingly, we emphasize that HOPDs would only receive payment for a dental service assigned to an APC when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment.

Second, we anticipate that we would continue to assess our policies for OPPS payment for dental services in future rulemaking. We believe that as we collect claims data, gather input from the public and interested parties, and learn more about the services performed in the HOPD setting, we will be able to make more informed decisions regarding payment rates, APC assignments, and status indicators for dental services.

The dental services for which we propose APC assignments in this proposed rule are those dental services described in the CY 2023 PFS final rule for which Medicare Part B payment can be made when they are inextricably linked to other covered services. Based on the dental services identified in that final rule, we generated a list of codes that describe those services for which we believe we need to propose APC assignments to ensure payment is available under the OPPS. To generate this list, we reviewed the dental codes that were specifically listed as examples of payable dental services in the CY 2023 PFS final rule (87 FR 69676). We also reviewed the clinical vignettes provided in the CY 2023 PFS final rule to identify whether there are other dental codes in addition to the dental code examples already identified for which we should propose APC assignments.

The CY 2023 PFS final rule amended § 411.15(i)(3)(i) to allow for payment under Medicare Part A and Part B for dental services, furnished in an inpatient or outpatient setting, that are inextricably linked to, and substantially related and integral to the success of, certain other covered medical services, including, but not limited to: (1) dental or oral examination as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and the necessary diagnostic and treatment services to eliminate an oral or dental infection prior to, or contemporaneously with, the organ transplant, cardiac valve replacement, or valvuloplasty procedure; (2) reconstruction of a dental ridge performed as a result of, and at the same time as, the surgical removal of a tumor; (3) the stabilization or immobilization of teeth in connection with the reduction of a jaw fracture, and dental splints only when used in conjunction with covered treatment of a covered medical condition such as dislocated jaw joints; and (4) the extraction of teeth to prepare the jaw for radiation treatment of neoplastic disease. For CY 2024, we established that Medicare Parts A and B payment may also be made for dental services, such as dental examinations, including necessary treatments, performed as part of a comprehensive workup prior to treatment for head and neck cancers. We include a proposal in the CY 2024 PFS proposed rule to codify this example under § 411.15(i)(3)(i). We identified dental services described in the regulation at § 411.15(i)(3)(i) and those that may be part of a comprehensive workup prior to treatment for head and neck cancers that could be payable under the OPPS if payment and coverage requirements are met. For example, consistent with § 411.15(i)(3)(A), which describes dental or oral examinations as part of a comprehensive workup prior to a Medicare covered organ transplant, cardiac valve replacement, or valvuloplasty procedure, we identified several codes describing dental examinations for which we propose APC assignments (*e.g.,* D0120, D0140, D0150, D0160, D0170, D0180, D0191, D0171). Section 411.15(i)(3)(C) describes services for the stabilization or immobilization of the teeth in connection with the reduction of a jaw fracture, and dental splints only when used with a covered treatment of a covered medical condition. We identified an additional 16 dental codes (*e.g.,* D7670–D7671; D4322; D5988) that we believe identify these services and for which we propose APC assignments.

While it is appropriate for CMS to assign certain dental codes to APCs for payment under the OPPS, we do not believe that every dental code should be assigned to an APC and made payable under the OPPS. For instance, there are services described by CDT codes that may already be described by existing CPT codes assigned to clinical APCs. When this is the case, we propose that HOPDs would use the existing CPT codes to bill for the services performed. We also are not proposing APC assignments for all dental codes, even if they describe dental services that are payable consistent with the policies and clarifications included in the CY 2023 PFS final rule. This is because under our regulation at 42 CFR 419.22, the following services are not paid under the OPPS (except when packaged as part of a bundled payment): physician services that meet the requirements of 42 CFR 415.102(a); nurse practitioner or clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act; physician assistant services, as

defined in section 1861(s)(2)(K)(i) of the Act; and services of an anesthetist as defined in § 410.9. We note that dentists are considered physicians for purposes of Medicare payment policy, including this regulation. There are a number of existing CDT codes that describe the professional services of dentists that could be paid under the PFS (*e.g.,* D9990–D9997), but that we do not believe are appropriate for payment under the OPPS. Therefore, we do not propose to assign CDT codes that describe professional services of dentists and other dental professionals to clinical APCs.

Finally, there are dental codes that we believe would not meet our current interpretation of dental services that may be inextricably linked to other covered medical services. For instance, there are CDT codes that describe removable prosthodontic procedures, including codes that describe complete or partial denture procedures (*e.g.,* D5110; D5120; D5211–D5214). Because denture procedures are not covered medical procedures under Medicare, we are not proposing to assign any dental codes describing denture procedures to clinical APCs.

In sum, in consultation with medical experts, we identified 229 dental codes as appropriate for payment under the OPPS when relevant conditions for payment and coverage are met. In addition to the dental codes already assigned to APCs, we propose to assign the 229 additional dental codes listed in Table 53 below to various clinical APCs for CY 2024:

BILLING CODE 4120–01–P

TABLE 53: DENTAL CODES PROPOSED FOR ASSIGNMENT TO CLINICAL APCS IN CY 2024

HCPCS Code	Description
D0120	Periodic oral evaluation
D0140	Limit oral eval problm focus
D0160	Extensv oral eval prob focus
D0170	Re-eval,est pt,problem focus
D0180	Comp periodontal evaluation
D0191	Assessment of a patient
D0171	Re-eval post-op visit
D1110	Dental prophylaxis adult
D7950	Mandible graft
D7340	Vestibuloplasty ridge extens
D7350	Vestibuloplasty exten graft
D7485	Surg reduct osseoustuberosit
D7310	Alveoplasty w/ extraction
D7311	Alveoloplasty w/extract 1-3
D7510	I&d absc intraoral soft tiss
D7473	Remove torus mandibularis
D7472	Removal of torus palatinus
D7520	I&d abscess extraoral
D7521	Incision/drain abscess extra
D7511	Incision/drain abscess intra
D7550	Removal of sloughed off bone
D7460	Rem nonodonto cyst to 1.25cm
D7461	Rem nonodonto cyst > 1.25 cm
D7272	Tooth transplantation
D7270	Tooth reimplantation
D7670	Closd rductn splint alveolus
D7671	Alveolus open reduction
D7770	Open reduc compd alveolus fx
D7771	Alveolus clsd reduc stblz te
D7874	Tmj arthroscopy disc reposit
D7922	Place intra-socket bio dress
D4323	Splint extra-coronal
D4322	Splint intra-coronal
D5988	Surgical splint
D2140	Amalgam one surface permanen
D2150	Amalgam two surfaces permane
D2160	Amalgam three surfaces perma
D2161	Amalgam 4 or > surfaces perm
D2330	Resin one surface-anterior
D2331	Resin two surfaces-anterior
D2332	Resin three surfaces-anterio

HCPCS Code	Description
D2335	Resin 4/> surf or w incis an
D2390	Ant resin-based cmpst crown
D2391	Post 1 srfc resinbased cmpst
D2392	Post 2 srfc resinbased cmpst
D2393	Post 3 srfc resinbased cmpst
D2394	Post >=4srfc resinbase cmpst
D2410	Dental gold foil one surface
D2420	Dental gold foil two surface
D2430	Dental gold foil three surfa
D2510	Dental inlay metalic 1 surf
D2520	Dental inlay metallic 2 surf
D2530	Dental inlay metl 3/more sur
D2542	Dental onlay metallic 2 surf
D2543	Dental onlay metallic 3 surf
D2544	Dental onlay metl 4/more sur
D2610	Inlay porcelain/ceramic 1 su
D2620	Inlay porcelain/ceramic 2 su
D2630	Dental onlay porc 3/more sur
D2642	Dental onlay porcelin 2 surf
D2643	Dental onlay porcelin 3 surf
D2644	Dental onlay porc 4/more sur
D2650	Inlay composite/resin one su
D2651	Inlay composite/resin two su
D2652	Dental inlay resin 3/mre sur
D2662	Dental onlay resin 2 surface
D2663	Dental onlay resin 3 surface
D2664	Dental onlay resin 4/mre sur
D2710	Crown resin-based indirect
D2712	Crown 3/4 resin-based compos
D2720	Crown resin w/ high noble me
D2721	Crown resin w/ base metal
D2722	Crown resin w/ noble metal
D2740	Crown porcelain/ceramic
D2750	Crown porcelain w/ h noble m
D2751	Crown porcelain fused base m
D2752	Crown porcelain w/ noble met
D2753	Crown porc fused to titanium
D2780	Crown 3/4 cast hi noble met
D2781	Crown 3/4 cast base metal
D2782	Crown 3/4 cast noble metal
D2783	Crown 3/4 porcelain/ceramic
D2790	Crown full cast high noble m
D2791	Crown full cast base metal
D2792	Crown full cast noble metal

HCPCS Code	Description
D2794	Crown-titanium
D2799	Interim crown
D2990	Resin infiltration of lesion
D2910	Recement inlay onlay or part
D2915	Recement cast or prefab post
D2920	Re-cement or re-bond crown
D2921	Reattach tooth fragment
D2929	Prefab porc/ceram crown pri
D2928	Prefab porc/cer crown perm
D2930	Prefab stnlss steel crwn pri
D2931	Prefab stnlss steel crown pe
D2932	Prefabricated resin crown
D2933	Prefab stainless steel crown
D2934	Prefab steel crown primary
D2940	Protective restoration
D2941	Int therapeutic restoration
D2949	Restorative foundation
D2950	Core build-up incl any pins
D2951	Tooth pin retention
D2952	Post and core cast + crown
D2953	Each addtnl cast post
D2954	Prefab post/core + crown
D2957	Each addtnl prefab post
D2955	Post removal
D2960	Labial veneer resin direct
D2961	Labial veneer resin indirect
D2962	Labial veneer porc indirect
D2971	Add proc construct new crown
D2975	Coping
D2980	Crown repair
D2981	Inlay repair
D2982	Onlay repair
D2983	Veneer repair
D1354	Int caries med app per tooth
D4210	Gingivectomy/plasty 4 or mor
D4211	Gingivectomy/plasty 1 to 3
D4212	Gingivectomy/plasty rest
D4230	Ana crown exp 4 or> per quad
D4231	Ana crown exp 1-3 per quad
D4240	Gingival flap proc w/ planin
D4241	Gngvl flap w rootplan 1-3 th
D4245	Apically positioned flap
D4249	Crown lengthen hard tissue
D4261	Osseous surg 1 to 3 teeth

HCPCS Code	Description
D4265	Bio mtrls to aid soft/os reg
D4266	Guided tiss regen resorble
D4267	Guided tiss regen nonresorb
D4274	Mesial/distal wedge proc
D4275	Non-auto graft 1st tooth
D4276	Con tissue w pedicle graft
D4277	Soft tissue graft firsttooth
D4278	Soft tissue graft addl tooth
D4283	Auto tissue graft addl tooth
D4285	Non-auto graft addl tooth
D4341	Periodontal scaling & root
D4342	Periodontal scaling 1-3teeth
D4346	Scaling gingiv inflammation
D4355	Full mouth debridement
D4381	Localized delivery antimicro
D4910	Periodontal maint procedures
D4920	Unscheduled dressing change
D4921	Gingival irrigation per quad
D4999	Unspecified periodontal proc
D3110	Pulp cap direct
D3120	Pulp cap indirect
D3220	Therapeutic pulpotomy
D3221	Gross pulpal debridement
D3222	Part pulp for apexogenesis
D3230	Pulpal therapy anterior prim
D3240	Pulpal therapy posterior pri
D3310	End thxpy, anterior tooth
D3320	End thxpy, premolar tooth
D3330	End thxpy, molar tooth
D3331	Non-surg tx root canal obs
D3332	Incomplete endodontic tx
D3333	Internal root repair
D3346	Retreat root canal anterior
D3347	Retreat root canal premolar
D3348	Retreat root canal molar
D3351	Apexification/recalc initial
D3352	Apexification/recalc interim
D3353	Apexification/recalc final
D3355	Pulpal regeneration initial
D3356	Pulpal regeneration interim
D3357	Pulpal regeneration complete
D3410	Apicoectomy – anterior
D3421	Root surgery premolar
D3425	Root surgery molar

HCPCS Code	Description
D3426	Root surgery ea add root
D3428	Bone graft peri per tooth
D3429	Bone graft peri each addl
D3430	Retrograde filling
D3431	Biological materials
D3432	Guided tissue regeneration
D3450	Root amputation
D3470	Intentional replantation
D3471	Surg rep root res anterior
D3472	Surg rep root res premolar
D3473	Surg rep root res molar
D3501	Surg exp root surf anterior
D3502	Surg exp root surf premolar
D3503	Surg exp root surf molar
D3910	Isolation- tooth w rubb dam
D3911	Intraorifice barrier
D3920	Tooth splitting
D3921	Decor or submerg erupt tooth
D3950	Canal prep/fitting of dowel
D0210	Intraor comprehensive series
D0220	Intraoral periapical first
D0230	Intraoral periapical ea add
D0273	Bitewings - three images
D0310	Dental saliography
D0320	Dental tmj arthrogram incl i
D0321	Other tmj images by report
D0322	Dental tomographic survey
D0330	Panoramic image
D0340	2d cephalometric image
D0350	Oral/facial photo images
D0364	Cone beam ct capt & interp
D0365	Cone beam ct interprete man
D0366	Cone beam ct interprete max
D0367	Cone beam ct interp both jaw
D0368	Cone beam ct interprete tmj
D0369	Max mri capture & interprete
D0370	Max ultrasound capt & interp
D0371	Sialoendoscopy capt & interp
D0380	Cone beam ct capture limited
D0381	Cone beam ct capt mandible
D0382	Cone beam ct capt maxilla
D0383	Cone beam ct both jaws
D0384	Cone beam ct capture tmj
D0385	Max mri image capture

HCPCS Code	Description
D0386	Max ultrasound image capture
D0701	Pano radio image
D0702	2d cephal radio image
D0703	2d oral/facial photo image
D0705	Extra oral post radio image
D0706	Intraoral occlus radio image
D0707	Intraoral periap radio image
D0708	Intraoral bite radio image
D0709	Intraoral comp image capture
D0393	Trtmnt simulation 3d image
D0394	Digital sub 2 or more images
D0395	Fusion 2 or more 3d images

BILLING CODE 4120–01–C

We request comments on the list of 229 dental codes that we propose to assign to APCs for OPPS payment for CY 2024. We also request comments on any additional dental codes that may fall within the scope of dental services for which payment is permitted as explained in the CY 2023 PFS final rule and provided in § 411.14(i)(3)(i), and for which payment should be made available under the OPPS when payment and coverage requirements are met.

3. Proposed APC Assignments for Additional Dental Codes

In accordance with section 1833(t)(2)(B) of the Act, services classified within each APC must be comparable clinically and with respect to the use of resources. Accordingly, when considering the appropriateness of an APC assignment for a code, we consider the clinical characteristics and resource costs of the service described by the code compared to other services in a clinical APC.

Consistent with our existing processes, we were able to crosswalk many of the dental codes to existing CPT codes assigned to APCs for purposes of assessing clinical similarity. For instance, we crosswalked certain tissue graft procedures (*e.g.,* D4270) to CPT code 41870 (gum graft). Because both are surgical procedures where gum tissue near the area of recession is used to cover and protect the exposed tooth root, the codes are clinically similar and we believe are appropriate for grouping within the same clinical APC (*i.e.,* APC 5163 (Level 3 ENT Procedures)). We also found clinical similarities between several dental imaging services and the services assigned to the various levels of the Imaging without Contrast APC series (*i.e.,* APCs 5521 (Level 1, Imaging without Contrast); 5522 (Level 2, Imaging without Contrast); and 5523 (Level 3, Imaging without Contrast)). For example, we crosswalked D0210 (Intraor complete film series) to CPT code 70320 (Full mouth x-ray of teeth) and therefore propose to assign D0210 to APC 5523 based on the crosswalk analysis.

With regard to resource similarity, because the 229 dental codes we propose to assign to APCs for CY 2024 were not previously paid under the OPPS, we do not have existing claims information to inform proposed APC placements based on resource costs. We considered gathering cost information from several non-Medicare data sources to aid in assigning the dental codes to APCs. For instance, we considered requesting cost information from the Department of Veterans Affairs (VA). However, the VA's dental reimbursement rates are proprietary and are not publicly available.

We also considered requesting data from State Medicaid agencies but found the available data too inconsistent and limited to be useful given that payment rates vary between states. Additionally, not every State Medicaid Agency provides the same dental benefits, so not every state would have cost information for each of the dental codes we propose for OPPS payment. Lastly, while many State Medicaid Agencies provide robust information on the dental benefits covered for Medicaid beneficiaries in their state, the fee schedules published by State Medicaid Agencies most likely include payments to practitioners only and would not be informative for our purposes of assigning payment rates under the OPPS.

Finally, we considered analyzing private insurance claims from third-party databases but determined that the cost information available would also not be relevant for OPPS ratesetting. For example, because most dental services covered by private insurance are provided in the office setting, there is a very limited number of claims that would be relevant for OPPS ratesetting purposes. Of the limited dental claims performed in the hospital setting, we learned that many of the dental services are performed in combination with several other services; therefore, it would be extremely difficult to isolate the facility fee payment for the dental services performed.

Although specific cost information is informative for making proposed APC assignments, it is not essential. For example, each quarter, after consultation with clinical experts, CMS assigns new CPT codes for which no cost information is available to APCs using crosswalk code analyses. Similar to our process for assigning new codes to APCs, we used a crosswalk code analysis and consulted with clinical experts to propose appropriate APC assignments for the 229 dental codes. In our conversations with the clinical experts, we discussed the clinical aspects of each dental service and learned about the resources, including supplies, used to perform each dental service, in order to more accurately identify crosswalk codes and propose APC assignments for them. We solicit comments regarding the proposed APC assignments for the dental codes for CY 2024. We refer readers to Addendum B to this proposed rule for the proposed CY 2024 APC assignments and associated payment rates for the dental codes. Addendum B is available via the internet on the CMS website.

4. Proposed Packaged Payment and Associated Status Indicators for Dental Codes

For CY 2024, we propose to package payments for dental services when they are performed with another covered dental or medical service to promote clinical resource efficiencies, a strategic goal of the OPPS. Given our understanding of the nature of dental practice and in consultation with our clinical experts, we believe packaged payments are appropriate for dental services paid under the OPPS. We are aware that it is common for several dental services to be performed together, or alongside other medical services, and submitted on one claim. Unlike medical specialties where often only one procedure is performed at a time, it is our understanding that it is common for a patient to undergo several surgical and non-surgical dental procedures on multiple teeth in one day, or for dental services to be performed contemporaneously with other medical services. For example, there are several non-invasive, non-surgical dental services, including a dental exam or X-ray, which would most likely be performed together with other more invasive dental services in the HOPD setting, rather than on their own. Because a dental exam or X-ray is likely to be performed in addition to other more invasive dental services in the HOPD setting, we believe packaging payment for dental codes describing dental exams and X-rays (*e.g.,* D0380–D0386) when performed with another service is appropriate and would further our strategic goal of encouraging hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. We also are aware that there are several dental services that are performed as part of a primary service, and therefore, we believe would also result in resource efficiencies if paid under the OPPS as a packaged payment. For example, CDT codes D3110 (pulp cap-direct (excluding final restoration)) and D3120 (pulp cap-indirect (excluding final restoration)) are typically performed as part of a restorative procedure (*e.g.,* a crown or amalgam). Thus, we believe it is appropriate to propose to package payment for CDT codes D3110 and D3120 with payment for the associated restorative procedures.

We believe our proposal to package payment for dental services under the OPPS is consistent with existing packaging payment principles in the OPPS. The OPPS regularly packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. We believe applying these principles to the furnishing of dental services in the OPPS is appropriate and would incentivize clinical resource efficiencies.

In addition to proposing to package payment for dental services to promote clinical resource efficiencies, there are also several dental services that would nevertheless be packaged under our regulation at 42 CFR 419.2(b). For example, payment for dental services described by add-on codes, like CDT code D2953 (each addtnl cast post) would be packaged under the OPPS consistent with § 419.2(b)(18). Therefore, we propose to package payment for CDT code D2953 with the procedures with which it is performed. We refer readers to the regulation at § 419.2(b) for a full list of items and services for which payment is packaged or conditionally packaged.

For CY 2024, we propose packaging payment for dental services under the OPPS by assigning the dental codes to packaged status indicators. We believe there are clinical resource efficiencies to be gained by packaging payments rather than separately paying for each dental service performed. We refer readers to Addendum B to this proposed rule for the proposed CY 2024 status indicators for the dental codes. Addendum B is available via the internet on the CMS website. For more information on all of the proposed status indicators for CY 2024, including explanations of the payment status for each proposed status indicator, we refer readers to Addendum D1 to this proposed rule.

5. Summary of OPPS Dental Proposal and Requests for Comments

In summary, we propose to assign an additional 229 dental codes describing various dental services to APCs for CY 2024. We are requesting comments on the list of codes we have identified for APC assignment and payment under the OPPS, including whether any of the 229 dental codes do not meet the requirements for payment for dental services included in the CY 2023 PFS final rule and regulation at § 411.15(i)(3)(i). Additionally, we are requesting comments on the proposed APC assignments for the dental codes for CY 2024. Finally, we propose to make packaged payments for dental services under the OPPS by assigning the dental codes describing those dental services to packaged status indicators. We believe packaging payment for dental services will incentivize clinical resource efficiencies, and we request comments on our proposal.

F. Use of Claims and Cost Report Data for CY 2024 OPPS and ASC Payment System Ratesetting Due to the PHE

As described in section I.A of this proposed rule, section 1833(t) of the Act requires the Secretary to annually review and update the payment rates for services payable under the Hospital OPPS. Specifically, section 1833(t)(9)(A) of the Act requires the Secretary to review not less often than annually and to revise the groups, the relative payment weights, and the wage and other adjustments described in paragraph (2) of the Act to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

When updating the OPPS payment rates and system for each rulemaking cycle, we primarily use two sources of information: the outpatient Medicare claims data and Healthcare Cost Report Information System (HCRIS) cost report data. The claims data source is the Outpatient Standard Analytic File, which includes final action Medicare outpatient claims for services furnished in a given calendar year. For the OPPS ratesetting process, our goal is to use the best available data for ratesetting to accurately estimate the costs associated with furnishing outpatient services and to set appropriate payment rates. Ordinarily, the best available claims data are the data from 2 years prior to the calendar year that is the subject of rulemaking. For the CY 2024 OPPS/ASC proposed rule ratesetting, the best available claims data would typically be the CY 2022 calendar year outpatient claims data processed through December 31, 2022. The cost report data source is typically the Medicare hospital cost report data files from the most recently available quarterly HCRIS file as we begin the ratesetting process. The best available cost report data used in developing the OPPS relative weights would ordinarily be from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking. For CY 2024 OPPS ratesetting, that would be cost report data from HCRIS extracted in December 2022, which would contain many cost reports ending in FY 2020 and 2021 based on each hospital's cost reporting period.

As discussed in the CY 2022 OPPS/ASC final rule with comment period, the standard hospital data we would have otherwise used for purposes of CY 2022 ratesetting included significant effects from the COVID–19 PHE, which

led to a number of concerns with using this data for CY 2022 ratesetting (86 FR 63751 through 63754). In section X.E of the CY 2022 OPPS/ASC proposed rule (86 FR 42188 through 42190), we noted a number of changes in the CY 2020 OPPS claims data we would ordinarily have used for ratesetting, likely as a result of the PHE. These changes included overall aggregate decreases in claims volume (particularly those associated with visits); significant increases in HCPCS code Q3014 (Telehealth originating site facility fee) in the hospital outpatient claims; and increases in certain PHE-related services, such as HCPCS code C9803, which describes COVID–19 specimen collection, and services assigned to APC 5801 (Ventilation Initiation and Management). As a result of the effects we observed from COVID–19 PHE-related factors in our claims and cost report data, as well as the increasing number of Medicare beneficiaries vaccinated against COVID–19, which we believed might make the CY 2022 outpatient experience closer to CY 2019 rather than CY 2020, we believed that CY 2020 data were not the best overall approximation of expected outpatient hospital services in CY 2022. Instead, we believed that CY 2019 data, as the most recent complete calendar year of data prior to the COVID–19 PHE, were a better approximation of expected CY 2022 hospital outpatient services. Therefore, in the CY 2022 OPPS/ASC final rule with comment period, we established a policy of using CY 2019 claims data and cost reports prior to the PHE in ratesetting for the CY 2022 OPPS with certain limited exceptions, such as where CY 2019 data were not available (86 FR 63753 through 63754).

For the CY 2023 OPPS proposed rule ratesetting, we conducted a review similar to the one we conducted for the CY 2022 OPPS ratesetting to determine the degree to which the effects of the COVID–19 PHE had continued or subsided in our claims data as well as what claims and cost report data would be appropriate for CY 2023 OPPS ratesetting. In general, we saw that the PHE had limited effect on the service and aggregate levels of volume as well as changes in the site of service of care, suggesting that, while clinical and billing patterns had not quite returned to their pre-PHE levels, they were beginning to do so.

For the CY 2023 OPPS/ASC final rule, while the effects of the COVID–19 PHE remained at both the aggregate and service levels for certain services, as discussed in that final rule with comment period (87 FR 48795 through 48798) and in FY 2023 IPPS proposed rule (87 FR 28123 through 28125), we recognized that future COVID–19 variants may have potentially varying effects. Therefore, we explained that we believed it was reasonable to assume that there would continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting, similar to the CY 2021 claims data. As a result, we proposed and finalized the use of CY 2021 claims for CY 2023 OPPS ratesetting.

We also used cost report data for the CY 2023 OPPS/ASC final rule (87 FR 72021) from the same set of cost reports we originally used in the CY 2021 OPPS/ASC final rule for ratesetting, which included cost reporting periods beginning in CY 2018 in most cases. We typically would have used the most updated available cost reports available in HCRIS in determining the CY 2023 OPPS/APC relative weights, which would have included cost reports with reporting periods that overlap with parts of CY 2020. However, noting that we observed significant impact at the service level when incorporating these cost reports into ratesetting and the effects on billing/clinical patterns, we finalized a policy to continue to use the same set of cost reports that we used in developing CY 2022 OPPS ratesetting.

For CY 2024 OPPS rulemaking, we continue to observe some differences at the aggregate and service level volumes in the CY 2022 claims data, relative to the pre-PHE period. However, we believe that it is reasonable to assume that there will be minor variations as a result of the COVID–19 PHE in claims data we use for ratesetting for the foreseeable future. As we have found that the effects are less pronounced, even relative to CY 2021 claims data used in CY 2023 OPPS ratesetting, we anticipate that most of the changes we observe represent a moderate continued return to pre-PHE volume and ongoing changes in clinical practice. As a result, we believe the CY 2022 claims data are appropriate for setting CY 2024 OPPS rates.

For CY 2024, we also evaluated the impact of using our standard update for cost reports. If we were to resume our typical process of using the most updated cost reports available, we would predominantly use cost report data from CY 2021, with some portion of the cost reports including cost reporting periods from prior years. While there are some differences compared to pre-PHE data, we generally observed limited impacts. Similar to the claims data approach, we believe it is reasonable to assume there will continue to be a limited influence of the COVID–19 PHE on the cost report data. However, as we continue to receive more updated cost report data, we believe that data will better reflect changes in provider charge and cost reporting structures. Given these factors, we believe that using the most recent cost report data available and resuming our regular cost report update process is appropriate for CY 2024 OPPS ratesetting.

As a result of our expectation that the CY 2022 claims that we would typically use are appropriate for establishing the CY 2024 OPPS rates, we propose to use the CY 2022 claims for the CY 2024 OPPS/ASC ratesetting process. In addition, we propose to resume our typical cost report update process of including the most recently available cost report data (primarily including cost reports with cost reporting periods including CY 2021). For the reasons previously discussed, we are generally not proposing any modifications to our usual OPPS ratesetting methodologies with regards to the use of updated claims and cost report data to account for the impact of COVID–19 on the ratesetting data.

G. Comment Solicitation on Payment for High-Cost Drugs Provided by Indian Health Service and Tribally-Owned Facilities

In the CY 2000 Final Rule (65 FR 18433), CMS implemented the prospective payment system for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In this rule, we noted that the Outpatient Prospective Payment System (OPPS) applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as ''outpatient services provided by hospitals of the Indian Health Service (IHS).'' While we stated that these services would ''continue to be paid under separately established rates which are published annually in the **Federal Register**,'' we indicated that our intent was ''to develop a plan that will help these facilities transition to the [O]PPS and will consult with the IHS to develop this plan.'' In the CY 2002 Final Rule (66 FR 59855), we finalized our revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4) specifying that hospitals of the IHS are excluded from the OPPS. However, we reiterated that this exclusion would only be in place until we developed a plan to include IHS hospitals under the OPPS.

In the intervening years, IHS and tribally-owned facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates. Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2023, the Medicare Outpatient per Visit Rate for the lower 48 States is $654 and $862 for Alaska.

IHS and tribally-owned facilities have continued to expand the breadth of services that they provide to their communities. Increasingly, this has meant providing higher-cost drugs along with more complex and expensive services. While the majority of IHS and tribally-owned facilities appear to be well served by the AIR, there are specialty facilities where the AIR might not be an adequate representation of the Medicare share of costs. If providing a drug or service costs a specialty facility exponentially more than the payment they receive through the AIR, it may not be financially feasible for these facilities to provide that drug or service. For example, the cost of providing expensive cancer drugs or oncology services could greatly exceed payment a specialty IHS facility receives through the AIR. We are concerned that, if payments under the AIR are inadequate for high-cost drugs, this could potentially threaten the viability of the few IHS and tribally-owned hospital outpatient specialty programs currently in operation and provide less incentive to IHS hospitals and tribally-owned facilities not currently offering specialty services to begin doing so.

Consequently, we seek comment on a number of potential policies to address payment to IHS and tribally-owned facilities for certain high-cost drugs and services. We are seeking comment on whether Medicare should pay separately for high-cost drugs provided by IHS and tribally-owned facilities. We would like input on:

- What universe of drugs would be appropriate for separate payment? How could CMS maintain that list and add or remove drugs from it?
- Would paying separately for all drugs over a certain cost threshold be easier to operationalize than paying separately for a specified list of drugs, while achieving the same policy objective? If so, what would be an appropriate cost threshold and how should it be updated?
- What would be the appropriate payment rate for any separately paid drugs? How should these rates be updated and should these rates be updated on an annual basis?
- Would the standard OPPS Average Sales Price (ASP) plus 6 percent payment methodology rate be too high of a payment rate if tribal and IHS facilities are able to acquire drugs at a discounted rate through the Federal Supply Schedule? Would a payment rate equivalent to the acquisition cost of the drug through the Federal Supply Schedule be a more appropriate approximation of the cost of these drugs?
- Should IHS remove the cost of any separately paid drugs from the calculation of the AIR? If the cost of these drugs was not removed from the AIR, would the government be paying twice for these drugs?
- How would IHS and tribally-owned facilities bill for separately paid drugs? Could they use the UB–04 form like standard OPPS hospitals?

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. We seek comment on whether an outlier policy might be an appropriate mechanism for addressing high-cost drugs and services provided by IHS and tribally-owned facilities.

We welcome input from interested parties on these policy ideas and any additional payment approaches that would enhance our ability to provide equitable payment for high-cost drugs and services provided by IHS and tribally-owned facilities.

XI. Proposed CY 2024 OPPS Payment Status and Comment Indicators

A. Proposed CY 2024 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

For CY 2024, we propose to change the definition of status indicator ''P'' from ''Partial Hospitalization'' to ''Partial Hospitalization or Intensive Outpatient Program'' in order to account for the proposed payment of intensive outpatient services beginning January 1, 2024, as discussed in section VIII.B of this proposed rule. We are not proposing to make any other changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2023 OPPS/ASC final rule with comment period, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

We solicit public comments on the proposed definitions of the OPPS payment status indicators for 2024.

The complete list of proposed CY 2024 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*.

The proposed CY 2024 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

B. Proposed CY 2024 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2024 OPPS. These comment indicators, ''CH,'' ''NC,'' ''NI,'' and ''NP,'' are in effect for CY 2023; and we propose to continue their use in CY 2024. The proposed CY 2024 OPPS comment indicators are as follows:

- ''CH''—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- ''NC''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we request comments in the proposed rule, final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- ''NI''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- ''NP''—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2024 are

listed in Addendum D2 to this proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.

We solicit public comments on our proposed definitions of the OPPS comment indicators for 2024.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make stakeholders aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2023 report.

A. OPPS Payment Rates Update

The March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress update Medicare OPPS payment rates by the amount specified in current law plus 1 percent. We refer readers to the March 2023 report for a complete discussion of this recommendation.[124] We appreciate MedPAC's recommendation and, as discussed further in section II.B of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

The March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' recommended that Congress should begin a transition to redistribute disproportionate share hospital and uncompensated care payments through the Medicare Safety-Net Index (MSNI). Additionally, MedPAC recommended that Congress add $2 billion to the MSNI pool of funds and distribute such funds through a percentage add-on to payments under the IPPS and OPPS.

In light of these recommendations, and in particular those concerning safety net hospitals, we look forward to working with Congress and seek comments on approaches CMS could take.

C. ASC Cost Data

In the March 2023 MedPAC ''Report to the Congress: Medicare Payment Policy,'' MedPAC reiterated its longstanding recommendation that Congress require ASCs to report cost data to enable the Commission to examine the growth of ASCs' costs over time and analyze Medicare payments relative to the costs of efficient providers. MedPAC suggested that such cost data would allow CMS to examine whether an existing Medicare price index is an appropriate proxy for ASC costs or whether an ASC-specific market basket should be developed, stating both the CPI–U and hospital market basket update likely do not reflect an ASC's cost structure. MedPAC contended that it is feasible for small facilities, such as ASCs, to provide cost information since other small facilities, such as home health agencies, hospices, and rural health clinics, currently furnish cost data to CMS. Further, ASCs in Pennsylvania submit cost and revenue data annually to a state agency to estimate margins for those ASCs, and that, as businesses, ASCs keep records of their costs for filing taxes and other purposes.[125]

While we recognize that the submission of cost data could place additional administrative burden on most ASCs, and we are not proposing any cost reporting requirements for ASCs in this proposed rule, we continue to seek public comment on methods that would mitigate the burden of reporting costs on ASCs while also collecting enough data to reliably use such data in the determination of ASC costs. Such cost data would be beneficial in establishing an ASC-specific market basket index for updating payment rates under the ASC payment system.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2023 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; and 87 FR 72054 through 72096).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC

[124] Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, p. 57. Available at: *https://www.medpac.gov*.

[125] Medicare Payment Advisory Committee. March 2023 Report to the Congress. Chapter 5: Ambulatory surgical center services, p. 163. Available at: *https://www.medpac.gov/wp-content/uploads/2023/03/Ch5_Mar23_MedPAC_Report_To_Congress_SEC.pdf*.

final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of, and payment rates for, covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle, is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2024 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in this proposed rule (and respond to those comments in the CY 2024 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2024 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2025 OPPS/ASC final rule with comment period).

2. April 2023 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2023 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2023 ASC quarterly update (Transmittal 11927, dated March 24, 2023, CR 13143), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 54 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023) of this proposed rule, lists the new Level II HCPCS codes that were implemented April 1, 2023. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2023, are assigned to comment indicator ''NP'' in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda are available via the internet on the CMS website.

- ASC Addendum AA: Proposed ASC Covered Surgical Procedures for CY 2024 (Including Surgical Procedures for Which Payment is Packaged),
- ASC Addendum BB: Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2024 (Including Ancillary Services for Which Payment is Packaged),
- ASC Addendum DD1: Proposed ASC Payment Indicators (PI) for CY 2024,
- ASC Addendum DD2: Proposed ASC Comment Indicators (CI) for CY 2024,
- ASC Addendum EE: Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2024, and
- ASC Addendum FF: Proposed ASC Device Offset Percentages for CY 2024
- Addendum O: Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2024

We are inviting public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2023 through the quarterly update CRs, as listed in Table 54 (New Level II HCPCS Codes for Ancillary Services Effective April 1, 2023) of this proposed rule. We propose to finalize their payment indicators in the CY 2024 OPPS/ASC final rule with comment period.

BILLING CODE 4120–01–P

TABLE 54: NEW LEVEL II HCPCS CODES FOR ASC COVERED ANCILLARY SERVICES EFFECTIVE APRIL 1, 2023

CY2023 HCPCS Code	CY 2023 Long Descriptor
C9145	Injection, aprepitant, (aponvie), 1 mg
C9146	Injection, mirvetuximab soravtansine-gynx, 1 mg
C9147	Injection, tremelimumab-actl, 1 mg
C9148	Injection, teclistamab-cqyv, 0.5 mg
C9149	Injection, teplizumab-mzwv, 5 mcg
J0208	Injection, sodium thiosulfate, 100 mg
J0218	Injection, olipudase alfa-rpcp, 1 mg
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1747	Injection, spesolimab-sbzo, 1 mg
J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg
J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to j9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to j9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to j9305, 10 mg
Q4265	Neostim tl, per square centimeter
Q4266	Neostim membrane, per square centimeter
Q4267	Neostim dl, per square centimeter
Q4268	Surgraft ft, per square centimeter
Q4269	Surgraft xt, per square centimeter
Q4270	Complete sl, per square centimeter
Q4271	Complete ft, per square centimeter
Q5127	Injection, pegfilgrastim-fpgk (stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg
Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg

3. July 2023 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2023 ASC quarterly update (Transmittal 12099, Change Request 13216, dated June 22, 2023), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 55 (New HCPCS Codes for Covered Surgical Procedures and Covered Ancillary Services Effective July 1, 2023) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2023. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2023, are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

TABLE 55: NEW HCPCS CODES FOR COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2023

CY2023 HCPCS Code	CY 2023 Long Descriptor
0793T	Percutaneous transcatheter thermal ablation of nerves innervating the pulmonary arteries, including right heart catheterization, pulmonary artery angiography, and all imaging guidance
0797T	Transcatheter insertion of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0800T	Transcatheter removal of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0803T	Transcatheter removal and replacement of permanent dual-chamber leadless pacemaker, including imaging guidance (eg, fluoroscopy, venous ultrasound, right atrial angiography, right ventriculography, femoral venography) and device evaluation (eg, interrogation or programming), when performed; right ventricular pacemaker component (when part of a dual-chamber leadless pacemaker system)
0809T	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, placement of transfixing device(s) and intra-articular implant(s), including allograft or synthetic device(s)
C9151	Injection, pegcetacoplan, 1 mg
J1440	Fecal microbiota, live - jslm, 1 ml
J1576	Injection, immune globulin (panzyga), intravenous, non-lyophilized (e.g., liquid), 500 mg
J1961	Injection, lenacapavir, 1 mg
J2329	Injection, ublituximab-xiiy, 1mg
J2427	Injection, paliperidone palmitate extended release (invega hafyera, or invega trinza), 1 mg
J7213	Injection, coagulation factor ix (recombinant), ixinity, 1 i.u.
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9058	Injection, bendamustine hydrochloride (apotex), 1 mg
J9059	Injection, bendamustine hydrochloride (baxter), 1 mg
J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg
J9259	Injection, paclitaxel protein-bound particles (american regent) not therapeutically equivalent to j9264, 1 mg
J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg

J9323	Injection, pemetrexed ditromethamine, 10 mg
J9347	Injection, tremelimumab-actl, 1 mg
J9350	Injection, mosunetuzumab-axgb, 1 mg
J9380	Injection, teclistamab-cqyv, 0.5 mg
J9381	Injection, teplizumab-mzwv, 5 mcg
Q5129	Injection, bevacizumab-adcd (vegzelma), biosimiliar, 10 mg

We are inviting public comments on the proposed payment indicators for the new HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services effective April 1, 2023, and July 1, 2023, through the quarterly update CRs, as listed in Tables 54 and 55. We propose to finalize the payment indicators in the CY 2024 OPPS/ASC final rule with comment period.

4. October 2023 HCPCS Codes Final Rule Comment Solicitation

For CY 2024, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2023, would be flagged with comment indicator ''NI'' in Addendum BB to the CY 2024 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2023. We will invite public comments in the CY 2024 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

5. January 2024 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2024 OPPS/ASC final rule with comment period, January 2024 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2024, we propose to continue our established policy of assigning comment indicator ''NI'' in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2024, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2024 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2025 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2024 ASC update, we received the CPT codes that will be effective January 1, 2024, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ''NP'' in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2024 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appear in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we include the 5-digit placeholder codes and their long descriptors for the new CY 2024 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled ''CY 2024 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code.'' We intend to include the final CPT code numbers the CY 2024 OPPS/ASC final rule with comment period.

In summary, we are soliciting public comments on the proposed CY 2024 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2024. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2024 OPPS/ASC final rule with comment period. The proposed payment indicators and comment indicators for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. The new CPT codes that will be effective January 1, 2024, are assigned to comment indicator ''NP'' in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim ASC payment assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 56, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

BILLING CODE 4120–01–P

TABLE 56: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2023	HCPCS (CPT and Level II codes)	April 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
July 2023	HCPCS (CPT and Level II codes)	July 1, 2023	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
October 2023	HCPCS (CPT and Level II codes)	October 1, 2023	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period
January 2024	CPT Codes	January 1, 2024	CY 2024 OPPS/ASC proposed rule	CY 2024 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2024	CY 2024 OPPS/ASC final rule with comment period	CY 2025 OPPS/ASC final rule with comment period

BILLING CODE 4120–01–C

6. ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, or NTIOLs.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator ''NI'' is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator ''NI'' also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator ''NP'' is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator ''NP'' also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The ''CH'' comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The ''CH'' comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ''K5''—Items, Codes, and Services for which pricing information and claims data are not available. No payment made.—to ASC Addendum DD1 (which is available via the internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

b. Proposed ASC Payment and Comment Indicators for CY 2024

For CY 2024, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2024 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2024, compared to the CY 2023 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator ''NP'' to indicate that these CPT and Level II HCPCS codes are open for comment as part of this CY 2024 OPPS/ASC proposed rule.

For CY 2024, we propose to add two ASC payment indicators for new proposed dental codes. Section XIII.D of this proposed rule describes the proposed addition of dental codes to the ASC CPL and ancillary services list for CY 2024. We propose to add specific dental payment indicators for more streamlined claims processing of the new dental codes, as these codes would require different billing mechanisms than non-dental procedures currently on the CPL. Separate payment indicators would allow MACs to more quickly and easily distinguish how these codes need to be processed. Proposed ASC payment indicators ''D1'' and ''D2'' are for the new dental codes that would be paid in CY 2024 and subsequent calendar years and would be added to Addendum DD1 (which is available via the internet on the CMS website) to indicate potentially payable dental services and procedures in the ASC setting. The first proposed payment indicator is ''D1''—''Ancillary dental service/item; no separate payment made.'' The ''D1'' indicator would indicate an ancillary dental procedure that would be performed integral to a separately payable dental surgical procedure with a payment indicator of ''D2.'' The second proposed payment indicator is ''D2''—''Non office-based dental procedure added in CY 2024 or later.'' The ''D2'' payment indicator would indicate a separately payable dental surgical procedure that would be subject to the multiple procedure reduction, but would not be designated as an office-based covered surgical procedure. Section XIII.D.2 of this proposed rule describes how these payment indicators would be used in claims processing for dental services. We solicit comment on these proposed new payment indicators, including whether their descriptors are appropriate and any considerations interested parties believe we should take into account when structuring payment for the procedures for which we propose to use payment indicators D1 and D2.

We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2024 update.

C. Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators ''G2'' and ''A2.'' Payment indicator ''A2'' was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator ''A2'' is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator ''A2'' because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b of this CY 2024 OPPS/ASC proposed rule, we update the payment amounts for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator ''J8'') is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4 of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators ''Q1'' and ''Q2'') describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator ''N1'') under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal—conditionally packaged in the OPPS (status indicator ''Q2'')—we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2024

We propose to update ASC payment rates for CY 2024 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4 of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators ''A2'' and ''G2.''

We propose to calculate payment rates for office-based procedures (payment indicators ''P2,'' ''P3,'' and ''R2'') and device-intensive procedures (payment indicator ''J8'') according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4 of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2024 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2024 MPFS nonfacility PE RVU-based amount or the proposed CY 2024 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2023, for CY 2024, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2'') will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments Under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain ''J1'' service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C–APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b of this proposed rule, we apply a complexity adjustment by promoting qualifying paired ''J1'' service code combinations or paired code combinations of ''J1'' services and add-on codes from the originating Comprehensive APC (C–APC) (the C–APC to which the designated primary service is first assigned) to the next higher paying C–APC in the same clinical family of C–APCs. A ''J1'' status indicator refers to a hospital outpatient service paid through a C–APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C–APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b of this proposed rule, in the originating C–APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator ''J1'' or add-on codes to determine if there are paired code combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of ''J1'' services, or combinations of a ''J1'' service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim to the next higher cost C–APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C–APC clinical family or assigned to the only C–APC in a clinical family. We do not create new C–APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C–APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C–APC would be the highest paying C–APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C–APC payment rate. If any add-on code reported in conjunction with the ''J1'' primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C–APC. We list the proposed complexity adjustments for ''J1'' and add-on code combinations for CY 2024, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices*).

(2) CY 2023 ASC Special Payment Policy for OPPS Complexity-Adjusted C–APCs

Comprehensive APCs cannot be adopted in the ASC payment system due to limitations of the ASC claims processing systems. Thus, we do not use the OPPS comprehensive services ratesetting methodology in the ASC payment system. Under the standard ratesetting methodology used for the ASC payment system, comprehensive ''J1'' claims that exist under the OPPS are treated the same as other claims that contain separately payable procedure codes. As comprehensive APCs do not exist under the ASC payment system, there is not a process similar to the OPPS complexity adjustment policy in the ASC payment system to provide higher payment for more complex code combinations. In the ASC payment system, when multiple procedures are performed together in a single operative session, most covered surgical procedures are subject to a 50-percent reduction for the lower-paying procedure (72 FR 66830). This multiple procedure reduction gives providers additional payment when they perform multiple procedures during the same session, while still encouraging providers to provide necessary services

as efficiently as possible. Add-on procedure codes are not separately payable under the ASC payment system and are always packaged into the ASC payment rate for the procedure. Unlike the multiple procedure discounting process used for other surgical procedures in the ASC payment system, providers do not receive any additional payment when they perform a primary service with a service corresponding to an add-on code in the ASC payment system.

Before CY 2023 rulemaking, we received suggestions from commenters requesting that we explore ways to increase payment to ASCs when services corresponding to add-on codes are performed with procedures, as certain code combinations may represent increased procedure complexity or resource intensity when performed together. For example, in the CY 2022 OPPS/ASC final rule with comment period, one commenter suggested that we modify the device-intensive criteria to allow packaged procedures that trigger a complexity adjustment under the OPPS to be eligible for device-intensive status under the ASC payment system (86 FR 63775). Based on our internal data review and assessment at that time, our response to that comment noted that we did not believe any changes were warranted to our packaging policies under the ASC payment system but that we would consider it in future rulemaking.

In the CY 2023 OPPS/ASC final rule, we evaluated the differences in payment in the OPPS and ASC settings for code pairs that included a primary procedure and add-on codes that were eligible for complexity adjustments under the OPPS and also performed in the ASC setting. When we compared the OPPS complexity-adjusted payment rate of these primary procedure and add-on code combinations to the ASC payment rate for the same code combinations, we found that the average rate of ASC payment as a percent of OPPS payment for these code combinations was significantly lower than 55 percent. We recognized that this payment differential between the C–APC-assigned code combinations eligible for complexity adjustments under the OPPS and the same code combinations under the ASC payment system could potentially create financial disincentives for providers to offer these services in the ASC setting, which could potentially result in Medicare beneficiaries encountering difficulties accessing these combinations of services in ASC settings. As noted above, our policy did not include additional payment for services corresponding to add-on codes, unlike our payment policy for multiple surgical procedures performed together, for which we provide additional payment under the multiple procedure reduction. However, these primary procedure and add-on code combinations that would be eligible for a complexity adjustment under the OPPS represented a more complex and costly version of the service, and we believed that providers not receiving additional payment under the ASC payment system to compensate for that increased complexity could lead to providers not being able to provide these services in the ASC setting, which could result in barriers to beneficiary access.

In order to address this issue, in the CY 2023 OPPS/ASC final rule (87 FR 72079 to 72080), we finalized a new ASC payment policy that would apply to certain code combinations in the ASC payment system where CMS would pay for those code combinations at a higher payment rate to reflect that the code combination is a more complex and costlier version of the procedure performed, similar to the way in which the OPPS APC complexity adjustment is applied to certain paired code combinations that exhibit materially greater resource requirements than the primary service. We finalized adding new regulatory text at § 416.172(h) to codify this policy.

We finalized that combinations of a primary procedure code and add-on codes that are eligible for a complexity adjustment under the OPPS (as listed in OPPS Addendum J) would be eligible for this payment policy in the ASC setting. Specifically, we finalized that the ASC payment system code combinations eligible for additional payment under this policy would consist of a separately payable surgical procedure code and one or more packaged add-on codes from the ASC Covered Procedures List (CPL) and ancillary services list. Add-on codes were assigned payment indicator ''N1'' (Packaged service/item; no separate payment made), as listed in the ASC addenda.

Regarding eligibility for this special payment policy, we finalized that we would assign each eligible code combination a new C-code, which we will refer to as an ''ASC complexity adjustment code,'' that describes the primary and the add-on procedure(s) performed. C-codes are unique temporary codes and are only valid for claims for HOPD and ASC services and procedures. Under our policy, we add these ASC complexity adjustment codes to the ASC CPL and the ancillary services list, and when ASCs bill an ASC complexity adjustment code, they receive a higher payment rate that reflects that the code combination is a more complex and costlier version of the primary procedure performed. We anticipated that the ASC complexity adjustment codes eligible for this payment policy would change slightly each year, as the complexity adjustment assignments change under the OPPS; and we expect we would add new ASC complexity adjustment codes each year accordingly. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72079 to 72080), we finalized new ASC complexity adjustment codes to add to the ASC CPL, which were listed in the ASC addenda. We also finalized adding new regulatory text at § 416.172(h)(1), titled ''Eligibility,'' to codify this policy.

We finalized the following payment methodology for this policy, which we reflected in new § 416.172(h)(2), titled ''Calculation of Payment.'' The ASC complexity adjustment codes are subject to all ASC payment policies, including the standard ASC payment system ratesetting methodology, meaning, they are treated the same way as other procedure codes in the ASC setting. For example, the multiple procedure discounting rules would apply to the primary procedure in cases where the services corresponding to the ASC complexity adjustment code are performed with another separately payable covered surgical procedure in the ASC setting. We finalized using the OPPS complexity-adjusted C–APC rate to determine the ASC payment rate for qualifying code combinations, similar to how we use OPPS APC relative weights in the standard ASC payment system ratesetting methodology. Under the ASC payment system, we used the OPPS APC relative payment weights to update the ASC relative payment weights for covered surgical procedures since ASCs do not submit cost reports. We then scaled those ASC relative weights for the ASC payment system to ensure budget neutrality. To calculate the ASC payment rates for most ASC covered surgical procedures, we multiplied the ASC conversion factor by the ASC relative payment weight. A more detailed discussion of this methodology is provided in the in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831).

We also finalized using the OPPS complexity-adjusted C–APC rate for each corresponding code combination to calculate the OPPS relative weight for each corresponding ASC complexity adjustment code, which we believed would appropriately reflect the complexity and resource intensity of

these ASC procedures being performed together. For ASC complexity adjustment codes that are not assigned device-intensive status (discussed below), we multiply the OPPS relative weight by the ASC budget neutrality adjustment (or ASC weight scalar) to determine the ASC relative weight. We then multiply the ASC relative weight by the ASC conversion factor to determine the ASC payment rate for each ASC complexity adjustment code. In short, we apply the standard ASC ratesetting process to the ASC complexity adjustment codes. We finalized adding new § 416.172(h)(2)(i) to codify this policy.

As discussed in section XIII.C.1.b of the CY 2023 OPPS/ASC final rule with comment period (87 FR 44708), certain ASC complexity adjustment codes under our policy may include a primary procedure that also qualifies for device-intensive status under the ASC payment system. For primary procedures assigned device-intensive status that are a component of an ASC complexity adjustment code created under this proposal, we believe it is appropriate for the ASC complexity adjustment code to retain the device-intensive status of the primary procedure as well as the device portion (or device offset amount) of the primary procedure and not the device offset percentage. For example, if the primary procedure has a device offset percentage of 31 percent (a device offset percentage of greater than 30 percent would be needed to qualify for device-intensive status) and a device portion (or device offset amount) of $3,000, ASC complexity adjustment codes that included this primary procedure would be assigned device-intensive status and a device portion of $3,000 to be held constant with the OPPS. We apply our standard ASC payment system ratesetting methodology to the non-device portion of the OPPS complexity-adjusted APC rate of the ASC complexity adjustment codes; that is, we apply the ASC budget neutrality adjustment and ASC conversion factor. We believe assigning device-intensive status and transferring the device portion from the primary procedure's ASC payment rate to the ASC complexity adjustment code's ASC payment rate calculation is consistent with our treatment of device costs and determining device-intensive status under the ASC payment system and is an appropriate methodology for determining the ASC payment rate. The non-device portion would be the difference between the device portion of the primary procedure and the OPPS complexity-adjusted APC payment rate for the ASC complexity adjustment code based on the ASC standard ratesetting methodology. Although this may yield results where the device offset percentage is not greater than 30 percent of the OPPS complexity-adjusted APC payment rate, we believe this is an appropriate methodology to apply where primary procedures assigned device-intensive status are a component of an ASC complexity adjustment code. As is the case for all device-intensive procedures, we apply the ASC standard ratesetting methodology to the OPPS relative weights of the non-device portion for any ASC complexity adjustment code eligible for payment under this proposal. That is, we would multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate. We finalized adding new § 416.172(h)(2)(ii) to codify this policy.

In order to include these ASC complexity adjustment codes in the budget neutrality calculations for the ASC payment system, we estimated the potential utilization for these ASC complexity adjustment codes. We do not have claims data for packaged codes in the ASC setting because ASCs do not report packaged codes under the ASC payment system. Therefore, we finalized estimating CY 2023 ASC utilization based upon how often these combinations are performed in the HOPD setting. Specifically, we used the ratio of the primary procedure volume to add-on procedure volume from CY 2021 OPPS claims and applied that ratio against ASC primary procedure utilization to estimate the increased spending as a result of our proposal for budget neutrality purposes. We believed this method would provide a reasonable estimate of the utilization of these code combinations in the ASC setting, as it is based on the specific code combination utilization in the OPPS. We anticipated that we would continue this estimation process until we have sufficient claims data for the ASC complexity adjustment codes that can be used to more accurately calculate code combination utilization in ASCs, likely for the CY 2025 rulemaking.

For CY 2024, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C–APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080). The full list of the proposed ASC complexity adjustment codes for CY 2024 can be found in the ASC addenda and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions, is published with the proposed rule on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices*. Because the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for this proposed payment policy has changed slightly from the previous year.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b of this proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal Low Volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a Low Volume APC. For items or services assigned to a Low Volume APC, we use up to four years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a Low Volume APC or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for this proposed rule, we propose to designate four clinical APCs and five brachytherapy APCs as Low Volume APCs under the ASC payment system. The four clinical APCs and five brachytherapy APCs shown in Table 57 of this proposed rule met our criteria of having fewer than 100 single claims in the claims year (CY 2022 for this proposed rule) and therefore, we propose that they would be subject to our universal Low Volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Eight of the nine APCs were designated as low volume APCs in CY 2023. In

addition, based on data for this CY 2024 OPPS/ASC proposed rule, APC 2642 (Brachytx, stranded, C–131) meets our criteria to be designated a Low Volume APC, and we propose to designate it as such for CY 2024.

TABLE 57: COST STATISTICS FOR PROPOSED LOW VOLUME APCS STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2024

APC	APC Description	CY 2022 Claims Available for Ratesetting	Geometric Mean Cost without Low Volume APC Designation	Proposed Median Cost	Proposed Arithmetic Mean Cost	Proposed Geometric Mean Cost	Proposed CY 2024 APC Cost
2632	Iodine I-125 sodium iodide	0	---*	$31.74	$61.83	$41.06	$61.83
2635	Brachytx, non-str, HA, P-103	21	$98.73	$58.38	$60.86	$54.77	$60.86
2636	Brachy linear, non-str, P-103	1	$89.34	$22.17	$57.15	$33.66	$57.15
2642	Brachytx, stranded, C-131	76	$99.92	$79.90	$100.65	$79.90	$100.65
2647	Brachytx, NS, Non-HDRIr-192	2	$452.28	$201.69	$403.29	$167.08	$403.29
5244	Level 4 Blood Product Exchanges and Related Services	1	$11,801.45	$44, 380.23	$38,586.00	$33,541.43	$44, 380.23
5494	Level 4 Intraocular Procedures	7	$13,296.11	$12,166.15	$12,060.74	$11,252.12	$12,166.15
5495	Level 5 Intraocular Procedures	69	$3,554.44	$3,276.94	$3,833.79	$3,148.13	$3,833.79
5496	Level 6 Intraocular Procedures	12	$12,649.58	$17,384.57	$16,695.84	$14,642.86	$17,384.57

* For the CY 2024 OPPS/ASC proposed rule, there were no CY 2022 claims that contain the HCPCS code assigned to APC 2632 (HCPCS code A9527) that were available for CY 2024 OPPS/ASC ratesetting.

2. Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators ''N,'' ''Q1,'' and ''Q2'') under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators ''Q1'' and ''Q2''). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indictor ''N1'') under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower

of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to ''Z2'' so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount (''Z3''), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to ''Z2'' for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoiced costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a ''device offset'' to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator ''Z2'' and revised the definition of payment indicator ''Z2'' to include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator ''Z3,'' and revised the definition of payment indicator ''Z3'' to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Services for CY 2024

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2024 OPPS and ASC payment rates and subsequent years' payment rates. We also propose to continue to set the CY 2024 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2024 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2024 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2024. For a discussion of the PFS rates, we refer readers to the CY 2024 PFS proposed rule, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule, we finalized our policy to designate as ''office-based'' those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that rule with payment indicator ''P2'' (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); ''P3'' (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or ''R2'' (Office-based surgical procedure added to ASC list in CY 2008 or later

without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2024 Proposed Office-Based Procedures

In developing this CY 2024 OPPS/ASC proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment (described in detail in section XIII.C.1.d of this proposed rule), including their potential designation as office-based. Historically, we would also review the most recent claims volume and utilization data (CY 2022 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2023 of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2'' in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63769 through 63773).

In our CY 2022 OPPS/ASC final rule with comment period (86 FR 63770), we discussed that we, historically, review the most recent claims volume and utilization data and clinical characteristics for all covered surgical procedures that were assigned a payment indicator of ''G2'' for CY 2021. For the CY 2022 OPPS/ASC final rule with comment period, the most recent claims volume and utilization data was CY 2020 claims. However, given our concerns with the use of CY 2020 claims data as a result of the COVID–19 PHE as further discussed in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63751 through 63754), we adopted a policy to not review CY 2020 claims data and did not assign permanent office-based designations to covered surgical procedures that were assigned a payment indicator of ''G2'' in CY 2021 (86 FR 63770 through 63771).

As discussed further in section X.D of the CY 2023 OPPS/ASC proposed rule (87 FR 44680 through 44682), in our review of the CY 2021 outpatient claims available for ratesetting for this CY 2023 OPPS proposed rule, we observed that many outpatient service volumes have partially returned to their pre-PHE levels; and it is reasonable to assume that there will continue to be some effects of the COVID–19 PHE on the outpatient claims that we use for OPPS ratesetting. As a result, we proposed to use the CY 2021 claims for CY 2023 OPPS ratesetting. Similarly, in the CY 2023 OPPS/ASC proposed rule (87 FR 44705 through 44708), we proposed to resume our historical practice and review the most recent claims and utilization data, in this case data from CY 2021 claims, for determining office-based assignments under the ASC payment system.

Our review of the CY 2022 volume and utilization data of covered surgical procedures currently assigned a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of two surgical procedures that we believed met the criteria for designation as permanently office-based. The data indicate that these procedures are performed more than 50 percent of the time in physicians' offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. The CPT codes that we propose to permanently designate as office-based for CY 2024 are listed in Table 58.

TABLE 58: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2024

CY 2023 CPT/HCPCS Code	Long Descriptor	CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	G2	P2*
38232	Bone marrow harvesting for transplantation; autologous	G2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

As discussed in the August 2, 2007 ASC final rule (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are

permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

We reviewed CY 2022 volume and utilization data for nine surgical procedures designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2.'' As shown in Table 59, for four of the nine surgical procedures, there were greater than 50 claims available and the volume and utilization data indicated these four procedures were performed predominantly in the office setting. Therefore, we propose to no longer designate the four procedures as temporarily office-based but to permanently designate these procedures as office-based and assign one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2.''

Additionally, for one of the nine surgical procedures, there were greater than 50 claims available; and the volume and utilization data indicated that this procedure—CPT code 64454 (Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed)—is not performed predominantly in the office setting. Therefore, as shown in Table 59, we propose to no longer designate this procedure as temporarily office-based. For CY 2024, we propose to assign this procedure a payment indicator of ''G2'' (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight).

TABLE 59: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2024

CY 2023 CPT/HCPCS Code	Long Descriptor	CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0402T	Collagen cross-linking of cornea, including removal of the corneal epithelium, when performed, and intraoperative pachymetry, when performed	R2	R2*
0512T	Extracorporeal shock wave for integumentary wound healing, including topical application and dressing care; initial wound	R2	R2*
64454	Injection(s), anesthetic agent(s) and/or steroid; genicular nerve branches, including imaging guidance, when performed	P3	G2
93985	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete bilateral study	P2	P2*
93986	Duplex scan of arterial inflow and venous outflow for preoperative vessel assessment prior to creation of hemodialysis access; complete unilateral study	P2	P2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

For four of the nine procedures that were designated as temporarily office-based in the CY 2023 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically ''P2,'' ''P3,'' or ''R2,'' there were fewer than 50 claims; therefore, there was an insufficient amount to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 60, we propose to continue to designate such procedures as temporarily office-based for CY 2024 and assign one of the office-based payment indicators.

For CY 2024, we propose to designate three new CY 2024 CPT codes for ASC covered surgical procedures as temporarily office-based—CPT placeholder codes 6X000, 64XX4, and X170T. After reviewing the clinical characteristics, utilization, and volume of related procedure codes or predecessor codes, we determined that the predecessor code for CPT placeholder code 6X000 (Suprachoroidal space injection of pharmacologic agent (separate procedure)) is CPT code 0465T (Suprachoroidal injection of a pharmacologic agent (does not include supply of medication)), which was

designated as an office-based procedure. Additionally, CPT placeholder code 64XX4 (Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator) is most similar to CPT code 0588T (Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve), which is also designated as temporarily office-based. Lastly, CPT placeholder code X170T (Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy) is most similar to CPT code 0101T (Extracorporeal shock wave involving musculoskeletal system, not otherwise specified) which is designated as an office-based surgical procedure. Therefore, as shown in Table 60, we propose to designate these three new CPT codes as temporarily office-based for CY 2024.

The procedures for which the proposed office-based designation for CY 2024 is temporary are indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*).

TABLE 60: PROPOSED CY 2024 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES DESIGNATED AS TEMPORARILY OFFICE-BASED

CY 2023 CPT/HCPCS Code / CY 2024 Placeholder Code	Long Descriptor	Final CY 2023 ASC Payment Indicator	Proposed CY 2024 ASC Payment Indicator*
0581T	Ablation, malignant breast tumor(s), percutaneous, cryotherapy, including imaging guidance when performed, unilateral	R2	R2*
6X000	Suprachoroidal space injection of pharmacologic agent (separate procedure)	NA	P3*
64XX4	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	NA	R2*
65785	Implantation of intrastromal corneal ring segments	P2	P3*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
X170T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	NA	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2024 PFS proposed rates. For a discussion of the proposed PFS rates, we refer readers to the CY 2024 PFS proposed rule.

4. Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

b. CY 2024 Proposed Device Intensive Procedures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), for CY 2019, we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

- All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

- Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;
- Is an integral part of the service furnished;
- Is used for one patient only;
- Comes in contact with human tissue;
- Is surgically implanted or inserted (either permanently or temporarily); and
- Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15–1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = ''N1'') procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code would retain the device portion of the primary procedure (also called the ''device offset amount'') and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

We are not proposing any changes related to designating surgical procedures as device-intensive under the ASC payment system for CY 2024.

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations, and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce

OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS ''FB'' modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS ''FC'' modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our ''FB''/''FC'' modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device, ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the ''FC'' modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. We are not proposing any changes to our policies related to no/cost full credit or partial credit devices for CY 2024.

5. Requirement in the Physician Fee Schedule CY 2024 Proposed Rule for HOPDs and ASCs To Report Discarded Amounts of Certain Single-Dose or Single-Use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–9, November 15, 2021) (''the Infrastructure Act'') amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The CY 2024 PFS proposed rule includes proposals to operationalize section 90004 of the Infrastructure Act, including a proposal that impacts hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023 notice in the OPPS/ASC proposed rule (87 FR 71988), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2024 Physician Fee Schedule proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals to implement Section 90004 of the Infrastructure Act to the CY 2024 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2024 PFS final rule with comment period. We note that this same notice appears in section V.C of this proposed rule.

6. Payment Amount and Beneficiary Coinsurance for Part B Rebatable Drugs

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169) was signed into law. Section 11101 of the IRA requires a Part B inflation rebate for a Part B rebatable drug if the Medicare payment amount, which is generally ASP plus 6 percent, if the drug rises at a rate that is faster than the rate of inflation. It also establishes changes to the Medicare payment rate and beneficiary coinsurance for such drugs under the ASC payment system. We refer the reader to the discussion of this proposed policy and proposed changes to the regulatory text, which are discussed in further detail in section II.H.I of this proposed rule.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Additions to the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by stakeholders.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021, CY 2022, and CY 2023 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805, 87 FR 72068 through 72076).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2024

Our current policy, which includes consideration of the general standards and exclusion criteria we have historically used to determine whether a surgical procedure should be added to the ASC CPL, is intended to ensure that surgical procedures added to the ASC CPL can be performed safely in the ASC setting on the typical Medicare beneficiary. In the CY 2023 OPPS/ASC final rule with comment period, we received requests to add dental surgeries furnished in the ASC setting to the ASC CPL (87 FR 71882). In response to these public comments, we noted that if a dental service is covered under Medicare Part B and meets the criteria for the ASC CPL (set forth at 42 CFR 416.166), then it could be added to the ASC CPL, and that we would take additional dental procedures into consideration for future rulemaking. For CY 2024, we conducted a review of procedures that currently are paid under the OPPS and not included on the ASC CPL. We also assessed procedures against our regulatory safety criteria at § 416.166. Based upon this review, we propose to update the ASC CPL by adding 26 dental surgical procedures to the list for CY 2024, as shown in Table 61 below.

After reviewing the clinical characteristics of these procedures, as well as consulting with stakeholders and multiple clinical advisors, we determined that these procedures are separately paid under the OPPS, would not be expected to pose a significant risk to beneficiary safety when performed in an ASC, and would not be expected to require active medical monitoring and care of the beneficiary at midnight following the procedure. These procedures are clinically similar to procedures in the CPT surgical range that we determined met the general standards for addition to the ASC CPL. These procedures are not excluded from being included on the ASC CPL because they do not generally result in extensive blood loss, require major or prolonged invasion of body cavities, commonly require systemic thrombolytic therapy, or directly involve major blood vessels; are not generally emergent or life-threatening in nature or designated as requiring inpatient care; or can only be reported using a CPT unlisted surgical procedure code or are otherwise excluded under Medicare. Therefore, we believe these procedures may all be appropriately performed in an ASC and propose to include them on the ASC CPL for CY 2024.

We note that there are statutory and regulatory limitations regarding Medicare coverage and payment for dental services. Section 1862(a)(12) of the Act generally precludes Medicare Part A or Part B payment for services in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting teeth (collectively referred to in this section as ''dental services''). The regulation at § 411.15(i) similarly prohibits payment for dental services. In the CY 2023 PFS final rule (87 FR 69663), we explained that there are certain instances where dental services are so integral to other medically necessary services that they are not in connection with dental services within the meaning of section 1862(a)(12) of the Act. Rather, such dental services are inextricably linked to, and substantially related to the clinical success of, other covered services (hereafter in this section, ''inextricably linked''). To provide greater clarity to current policies, the CY

2023 PFS final rule finalized: (1) a clarification of our interpretation of section 1862(a)(12) of the Act to permit payment for dental services that are inextricably linked to other covered services; (2) clarification and codification of certain longstanding Medicare FFS payment policies for dental services that are inextricably linked to other covered services; (3) that, beginning for CY 2023, Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered organ transplant, cardiac valve replacement, or valvuloplasty procedures; and, (4) beginning for CY 2024, that Medicare Parts A and B payment can be made for certain dental services inextricably linked to Medicare-covered services for treatment of head and neck cancers (87 FR 69670 through 69671). For the ASC setting, services must meet all applicable Medicare conditions for coverage and payment to be paid by Medicare, including those as specified under the CY 2023 PFS final rule (87 FR 69687 through 69688) and § 411.15(i)(3). Medicare payment may be made in the ASC setting for dental services for which payment may be made under Medicare Part B, paid under the OPPS, and that meet the ASC CPL criteria. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. We also clarify that adding dental procedures to the ASC CPL does not serve as a coverage determination for dental services under general anesthesia. We direct readers to the CY 2024 PFS proposed rule for additional discussion of Medicare coverage and payment for dental services, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

HCPCS code G0330 covers facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (*e.g.,* general, intravenous sedation (monitored anesthesia care)) and use of an operating room. While G0330 has a broader code descriptor than most of the dental codes proposed to be added to the ASC CPL, we propose to add G0330 to the ASC CPL. We also propose that it can only be billed when accompanied by at least one covered ancillary dental service on a specific and definitive list of CDT codes, which can be found in ASC Addendum BB with payment indicator ''D1.'' [126] Performance of at least one of these covered ancillary services is integral to each of the surgical procedures that correspond to G0330. For example, if a patient requires a full mouth debridement to enable a comprehensive periodontal evaluation and diagnosis on a subsequent visit, as described by covered ancillary code CDT code D4355, or to enable excision of a gum lesion, as described by CPT 41827, and this procedure needs to be performed under anesthesia due to patient-specific circumstances, the ASC would bill G0330 with covered ancillary code D4355 to perform the debridement under anesthesia or G0330 with covered ancillary code 41827 to perform the excision service under anesthesia. Additionally, as previously noted, when G0330 is billed on a claim, MACs would determine whether payment can be made for the procedure under § 411.15(i)(3), and whether the procedure was reasonable and medically necessary before providing payment for the procedure. This claims processing mechanism is discussed in further detail in the covered ancillary services section (section XIII.D.2 of this proposed rule). Procedures assigned to payment indicator ''D2'', other than HCPCS code G0330, are not required to be billed with a covered ancillary procedure assigned to payment indicator ''D1'' in order to receive payment for the procedure.

We continue to focus on maximizing patient access to care by adding procedures to the ASC CPL when appropriate. While expanding the ASC CPL offers benefits, such as preserving the capacity of hospitals to treat more acute patients and promoting site neutrality, we also believe that any additions to the CPL should be added in a carefully calibrated fashion to ensure that the procedure is safe to be performed in the ASC setting for a typical Medicare beneficiary. We expect to continue to gradually expand the ASC CPL, as medical practice and technology continue to evolve and advance in future years. We encourage stakeholders to submit procedure recommendations to be added to the ASC CPL, particularly if there is evidence that these procedures meet our criteria and can be safely performed in the ASC setting.

BILLING CODE 4120–01–P

[126] See section XIII.B.6.b for a detailed discussion of payment indicators ''D1'' and ''D2.''

TABLE 61: CY 2024 PROPOSED SURGICAL PROCEDURES FOR THE ASC CPL

CY 2024 CPT/HCPCS/CDT Code	CY 2024 Long Descriptor
D4210	Gingivectomy or gingivoplasty - four or more contiguous teeth or tooth bounded spaces per quadrant
D4211	Gingivectomy or gingivoplasty - one to three contiguous teeth or tooth bounded spaces per quadrant
D4212	Gingivectomy or gingivoplasty to allow access for restorative procedure, per tooth
D4260	Osseous surgery (including elevation of a full thickness flap entry and closure) - four or more contiguous teeth or tooth bounded spaces per quadrant
D4263	Bone replacement graft - retained natural tooth - first site in quadrant
D4270	Pedicle soft tissue graft procedure
D4273	Autogenous connective tissue graft procedure (including donor and recipient surgical sites) first tooth, implant, or edentulous tooth position in graft
D7111	Extraction, coronal remnants - primary tooth
D7140	Extraction – erupted tooth or exposed root (elevation and/or forcep removal)
D7210	Surgical removal of an erupted tooth requiring removal of bone and/or sectioning of tooth and including elevation of mucoperiosteal flap if indicated
D7220	Removal of impacted tooth – soft tissue
D7230	Removal of impacted tooth – partially bony
D7240	Removal of impacted tooth – completely bony
D7241	Removal of impacted tooth – completely bony, with unusual surgical complications
D7250	Surgical removal of residual tooth roots (cutting procedure)
D7270	Tooth reimplantation and/or stabilization of accidentally evulsed or displaced tooth

BILLING CODE 4120–01–C

3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS

may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2023, but will be packaged under the CY 2024 OPPS, we would also package the ancillary service under the ASC payment system for CY 2024 to maintain consistency with the OPPS. Comment indicator ''CH'' is used in Addendum BB (which is available via the internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2024.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2024 can be found in section XIII.B of this proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2024 are also included in Addendum BB to this proposed rule (which is available via the internet on the CMS website).

Claims Processing Limitations for Covered Ancillary Procedures Performed With G0330

HCPCS code G0330 (Facility services for dental rehabilitation procedure(s) performed on a patient who requires monitored anesthesia (*e.g.,* general, intravenous sedation (monitored anesthesia care) and use of an operating room)) is a proposed addition to the ASC CPL for CY 2024, as discussed in section XIII.D.1 of this proposed rule. In ASC Addendum BB, there is a specific and definitive list of covered ancillary dental services with proposed payment indicator of ''D1.'' For CY 2024, we propose that G0330 could only be billed with a covered ancillary procedure that has the proposed payment indicator of ''D1,'' indicating an ancillary dental service or item with no separate payment made. This limitation would ensure that only covered ancillary services we have evaluated for safety in the ASC setting can be performed with G0330. While HCPCS code G0330 must be billed with a covered ancillary procedure with a proposed payment indicator of ''D1'', these covered ancillary procedures can be billed with procedures other than G0330. When billed with procedures other than G0330, these procedures would be packaged in accordance with our policy for covered ancillary procedures. The fact that a drug, device, procedure, or service is assigned a HCPCS code and a payment rate under the ASC payment system indicates only how the product, procedure, or service may be paid if covered by the program. MACs will be involved in the final decision regarding whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. Therefore, even if a code describing a dental service has an associated payment rate on the ASC CPL, Medicare will only make payment for the service if it meets applicable requirements. More detail on the proposed ASC dental indicators can be found in section XIII.B.6 of this proposed rule.

E. ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs, Biologicals, and Devices

1. Background on OPPS/ASC Non-Opioid Pain Management Packaging Policies

On October 24, 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act (Pub. L. 115–271) was enacted. Section 1833(t)(22)(A)(i) of the Act, as added by section 6082(a) of the SUPPORT Act, states that the Secretary must review payments under the OPPS for opioids and evidence based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. As part of this review, under section 1833(t)(22)(A)(iii) of the Act, the Secretary must consider the extent to which revisions to such payments (such as the creation of additional groups of covered outpatient department (OPD) services to separately classify those procedures that utilize opioids and non-opioid alternatives for pain management) would reduce the payment incentives for using opioids instead of non-opioid alternatives for pain management. In conducting this review and considering any revisions, the Secretary must focus on covered OPD services (or groups of services) assigned to C–APCs, APCs that include surgical services, or services determined by the Secretary that generally involve treatment for pain management. If the Secretary identifies revisions to payments pursuant to section 1833(t)(22)(A)(iii) of the Act, section 1833(t)(22)(C) of the Act requires the Secretary to, as determined appropriate, begin making revisions for services furnished on or after January 1, 2020. Revisions under this paragraph are required to be treated as adjustments for purposes of paragraph (9)(B) of the Act, which requires any adjustments to be made in a budget neutral manner. Section 1833(i)(8) of the Act, as added by section 6082(b) of the SUPPORT Act, requires the Secretary to conduct a similar type of review as required for the OPPS and to make revisions to the ASC payment system in an appropriate manner, as determined by the Secretary.

For a detailed discussion of rulemaking on non-opioid alternatives prior to CY 2020, we refer readers to the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59345; 83 FR 58855 through 58860).

For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), as required by section 1833(t)(22)(A)(i) of the Act, we reviewed payments under the OPPS for opioids and evidence-based non-opioid alternatives for pain management (including drugs and devices, nerve blocks, surgical injections, and neuromodulation) with a goal of ensuring that there are not financial incentives to use opioids instead of non-opioid alternatives. For the CY 2020 OPPS/ASC proposed rule (84 FR 39423 through 39427), we proposed to continue our policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they are furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting.

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61173 through 61180), after reviewing data from stakeholders and Medicare claims data, we did not find compelling evidence to suggest that revisions to our OPPS payment policies for non-opioid pain management alternatives were necessary for CY 2020. We finalized our proposal to continue to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when furnished in the ASC setting for CY 2020. Under this policy, for CY 2020, the only drug that qualified for separate payment in the ASC setting as a non-opioid pain management drug that

functions as a surgical supply was Exparel.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85896 through 85899), we continued the policy to pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures when they were furnished in the ASC setting and to continue to package payment for non-opioid pain management drugs that function as surgical supplies in the performance of surgical procedures in the hospital outpatient department setting for CY 2021. For CY 2021, only Exparel and Omidria met the criteria as non-opioid pain management drugs that function as surgical supplies in the ASC setting, and received separate payment under the ASC payment system.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63483), we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS/ASC drug packaging threshold; and we finalized our proposed regulation text changes at 42 CFR 416.164(a)(4) and (b)(6), 416.171(b)(1), and 416.174 as proposed.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72089), we determined that five products were eligible for separate payment in the ASC setting under our final policy for CY 2022. We noted that future products, or products not discussed in that rulemaking that may be eligible for separate payment under this policy, would be evaluated in future rulemaking (86 FR 63496). Table 62 lists the five drugs that met our finalized criteria established in CY 2022 to receive separate payment under the ASC payment system when furnished in the ASC setting for CY 2023 as described in the CY 2023 final rule with comment period (86 FR 63496).

BILLING CODE 4120–01–P

TABLE 62: SUMMARY OF FINALIZED PRODUCTS MEETING CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2023

HCPCS Code	Brand Name	Long Descriptor	CY 2023 OPPS Status Indicator (SI)*	CY 2023 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2
C9144	Posimir	Injection, bupivacaine (posimir), 1 mg	N	K2

*Please see the CY 2023 OPPS/ASC final rule with comment period addenda, specifically, the ASC Addenda BB for final applicable payment rates, OPPS Addenda D1 for final SI definitions, and ASC Addenda DD1 for final PI definitions. All are available via the internet on the CMS website.

BILLING CODE 4120–01–C

2. Proposed CY 2024 Qualification Evaluation for Separate Payment of Non-Opioid Pain Management Drugs and Biologicals That Function as a Surgical Supply

As noted above, in the CY 2022 OPPS/ASC final rule with comment period, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for non-opioid pain management drugs that function as surgical supplies when they are furnished in the ASC setting, are FDA-approved, have an FDA-approved indication for pain management or as an analgesic, and have a per-day cost above the OPPS drug packaging threshold beginning on or after January 1, 2022. For CY 2024, the OPPS drug packaging threshold is proposed to be $140. For more information on the drug packaging threshold, see section V.B.1.a of this CY 2024 OPPS/ASC proposed rule.

In the CY 2023 OPPS/ASC final rule, we finalized a clarification of our policy by codifying the two additional criteria for separate payment for non-opioid pain management drugs and biologicals that function as surgical supplies in the regulatory text at § 416.174 as a technical change. First, we finalized at

new § 416.174(a)(3) that non-opioid pain management drugs or biologicals that function as a supply in a surgical procedure are eligible for separate payment if the drug or biological does not have transitional pass-through payment status under § 419.64. In the case where a drug or biological otherwise meets the requirements under § 416.174 and has transitional pass-through payment status that will expire during the calendar year, the drug or biological would qualify for separate payment under § 416.174 during such calendar year on the first day of the next calendar year quarter after its pass-through status expires. Second, we finalized that new § 416.174(a)(4) would reflect that the drug or biological must not already be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174.

The following sections include the non-opioid alternatives of which we are aware and our evaluations of whether these non-opioid alternatives meet the criteria established at § 416.174. We welcome stakeholder comment on these evaluations.

(a) Proposed Annual Eligibility Re-Evaluations of Non-Opioid Alternatives That Were Separately Paid in the ASC Setting During CY 2023

In the CY 2023 final rule with comment period, we finalized that five drugs would receive separate payment in the ASC setting for CY 2023 under the policy for non-opioid pain management drugs and biologicals that function as surgical supplies (86 FR 63496). These drugs are described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0. mg*), HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), HCPCS code C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), and HCPCS code C9144 (*Injection, bupivacaine (posimir), 1 mg)*).

We re-evaluated these products outlined in the previous paragraph against the criteria specified in § 416.174, including the technical clarifications we proposed to that section, to determine whether they continue to qualify for separate payment in CY 2024. Based on our evaluation, we propose that the drugs described by HCPCS codes C9290, J1096, J1097, and C9089 continue to meet the required criteria and should receive separate payment in the ASC setting. We propose that the drug described by HCPCS code C9144 would not receive separate payment in the ASC setting under this policy, as this drug will be separately payable during CY 2024 under OPPS transitional pass-through status. Please see section V.A (OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals) of this CY 2024 OPPS/ASC proposed rule for additional details on the pass-through status of HCPCS code C9144. We welcome comment on our evaluations below.

(b) Proposed Eligibility Evaluation for the Separate Payment of Exparel

Based on our internal review, we believe that Exparel, described by HCPCS code C9290 (*Injection, bupivacaine liposome, 1 mg*), meets the criteria described at § 416.174; and we propose to continue paying separately for it under the ASC payment system for CY 2024. Exparel was approved by the FDA with a New Drug Application (NDA #022496) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on October 28, 2011.[127] Exparel's FDA-approved indication is ''in patients 6 years of age and older for single-dose infiltration to produce postsurgical local analgesia'' and ''in adults as an interscalene brachial plexus nerve block to produce postsurgical regional analgesia.'' [128] No component of Exparel is opioid-based. Accordingly, we propose that Exparel meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Exparel exceeds the proposed $140 per-day cost threshold. Therefore, we propose that Exparel meets the criterion described at § 416.174(a)(2). Additionally, Exparel will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Exparel meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we believe that Exparel meets the criteria described at § 416.174; and we propose to continue making separate payment for it as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(c) Proposed Eligibility Evaluation for the Separate Payment of Omidria

Based on our internal review, we believe that Omidria, described by HCPCS code J1097 (*Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml*), meets the criteria described at § 416.174(a), and we propose to continue paying separately for it under the ASC payment system for CY 2024. Omidria was approved by the FDA with a New Drug Application (NDA #205388) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on May 30, 2014.[129] Omidria's FDA-approved indication is as ''an alpha 1-adrenergic receptor agonist and nonselective cyclooxygenase inhibitor indicated for: Maintaining pupil size by preventing intraoperative miosis; Reducing postoperative pain.'' [130] No component of Omidria is opioid-based. Accordingly, we propose that Omidria meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Omidria exceeds the proposed $140 per-day cost threshold. Therefore, we propose that Omidria meets the criterion described at § 416.174(a)(2). Additionally, we believe that Omidria will not have transitional pass-through payment status under § 419.64 in CY 2024, nor will it be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Omidria meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Omidria meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(d) Proposed Eligibility Evaluation for the Separate Payment of Xaracoll

Based on our internal review, we believe Xaracoll, described by C9089 (*Bupivacaine, collagen-matrix implant, 1 mg*), meets the criteria described at § 416.174(a), and we propose to continue paying separately for it under the ASC payment system for CY 2023. Xaracoll was approved by the FDA with a New Drug Application (NDA #

[127] Exparel. FDA Letter. 28 October 2011. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2011/022496s000ltr.pdf.*

[128] Exparel. FDA Package Insert. 22 March 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/022496s035lbl.pdf.*

[129] Omidria. FDA Letter. 30 May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2014/205388Orig1s000ltr.pdf.*

[130] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*

209511) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on August 28, 2020.[131] Xaracoll is ''indicated in adults for placement into the surgical site to produce postsurgical analgesia for up to 24 hours following open inguinal hernia repair.'' [132] No component of Xaracoll is opioid-based. Accordingly, we propose that Xaracoll meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Xaracoll exceeds the proposed $140 per-day cost threshold. Therefore, we propose that Xaracoll meets the criterion described at § 416.174(a)(2). Additionally, at this time we do not believe that Xaracoll will have transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that Xaracoll meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Xaracoll meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(e) Proposed Eligibility Evaluation for the Separate Payment of Dextenza

Based on our internal review, we believe Dextenza, described by HCPCS code J1096 (*Dexamethasone, lacrimal ophthalmic insert, 0.1 mg*), meets the criteria described at § 416.174; and we propose to provide separate payment for it under the ASC payment system for CY 2024. Dextenza was approved by the FDA with a New Drug Application (NDA # 208742) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on November 30, 2018.[133] Dextenza's FDA-approved indication is as ''a corticosteroid indicated for the treatment of ocular pain following ophthalmic surgery'' and ''the treatment of ocular itching associated with allergic conjunctivitis.'' [134] No component of Dextenza is opioid-based. Accordingly, we propose that Dextenza meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Dextenza exceeds the proposed $140 per-day cost threshold. Therefore, we propose that Dextenza meets the criterion described at § 416.174(a)(2). Additionally, we believe that Dextenza will not have transitional pass-through payment status under § 419.64 in CY 2024, nor do we believe it will otherwise be separately payable in the OPPS or ASC payment system under a policy other than the one specified in § 416.174. Therefore, we propose that Dextenza meets the criteria in the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Dextenza meets the criteria described at § 416.174 and should receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

(f) Proposed Eligibility Evaluation for the Separate Payment of Posimir

Based on our internal review, we do not believe that Posimir, described by HCPCS code C9144 (*Injection, bupivacaine (Posimir), 1 mg*), meets the criteria described at § 416.174(a); and we do not propose to continue paying separately for it under the ASC payment system for CY 2024. Posimir was approved by the FDA with a New Drug Application (NDA # 204803) under section 505(c) of the Federal Food, Drug, and Cosmetic Act on February 1, 2021.[135] Posimir contains an amide local anesthetic and is indicated in adults for administration into the subacromial space under direct arthroscopic visualization to produce post-surgical analgesia for up to 72 hours following arthroscopic subacromial decompression.'' [136]

No component of Posimir is opioid-based. Accordingly, we propose that Posimir meets the criterion described at § 416.174(a)(1). Under the methodology described at V.B.1.a. of this proposed rule, the per-day cost of Posimir exceeds the proposed $140 per-day cost threshold. Therefore, we propose that Posimir meets the criterion described at § 416.174(a)(2). However, Posimir will have transitional pass-through payment status under § 419.64 in CY 2024, and it will be otherwise separately payable in the OPPS or ASC payment system in CY 2024 under a policy other than the one specified in § 416.174. Therefore, we propose that Posimir does not meet the criteria at the regulation text at § 416.174(a)(3) and (4).

Based on the above discussion, we propose that Posimir does not meet the criteria in the regulation text at § 416.174(a)(3) and (4), and should not receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024. However, HCPCS code C9144 will continue to receive separate payment under its pass-through status as outlined in section V of this proposed rule.

Table 63 below lists the four drugs that we propose as eligible to receive separate payment as a non-opioid pain management drug that functions as a supply in a surgical procedure under the ASC payment system for CY 2024.

[131] Xaracoll. FDA Letter. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/209511Orig1s000ltr.pdf.*

[132] Xaracoll. FDA Labeling. August 2020. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209511s000lbl.pdf.*

[133] Dextenza. FDA Letter. November 2018. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2018/208742Orig1s000Approv.pdf.*

[134] Dextenza. FDA Labeling. October 2021. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*

[135] Posimir. FDA Approval Letter. *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2021/204803Orig1s000ltr.pdf.*

[136] Posimir. FDA Package Insert. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/204803Orig1s001lbl.pdf.*

TABLE 63: SUMMARY OF PRODUCTS PROPOSED TO MEET CMS'S CRITERIA FOR SEPARATE PAYMENT IN THE ASC SETTING UNDER THE NON-OPIOID PAIN MANAGEMENT DRUGS THAT FUNCTION AS A SURGICAL SUPPLY PACKAGING POLICY FOR CY 2024

HCPCS Code	Brand Name	Long Descriptor	CY 2024 OPPS Status Indicator (SI)*	CY 2024 ASC Payment Indicator (PI)*
C9290	Exparel	Injection, bupivacaine liposome, 1 mg	N	K2
J1097	Omidria	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	N	K2
J1096	Dextenza	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	N	K2
C9089	Xaracoll	Bupivacaine, collagen-matrix implant, 1 mg	N	K2

*Please see ASC Addenda BB for applicable payment rates, OPPS Addenda D1 for SI definitions, and ASC Addenda DD1 for PI definitions. All are available via the internet on the CMS website.

3. Comment Solicitation on New Products That Meet the Criteria

We solicit comment on additional non-opioid pain management drugs and biologicals that function as surgical supplies that may meet the criteria specified in § 416.174 and qualify for separate payment under the ASC payment system. We encouraged commenters to include an explanation of how the drug or biological meets the eligibility criteria in § 416.174. If we find that any additional drugs or biologicals described by commenters do satisfy the criteria established at § 416.174, we will finalize their separate payment status for CY 2024 in the ASC setting in the CY 2024 OPPS/ASC final rule with comment period.

F. Comment Solicitation on Access to Non-Opioid Treatments for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, subparagraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Subparagraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Because the additional payments are required to begin on January 1, 2025, we plan to include our proposals to implement the section 4135 amendments in the CY 2025 OPPS/ASC proposed rule. We specifically seek comment on the issues discussed in the following sections as well as comments on the implementation of all facets of this provision.

2. CY 2025 Comment Solicitation

a. Potential Qualifying Drugs, Biologicals, and Devices

In preparation for implementing section 4135 of the CAA, 2023, for CY 2025, we seek comment on any drug, biological, or medical device that a commenter believes would meet the definition of a non-opioid treatment for pain relief under section

1833(t)(16)(G)(iv) of the Act. We encourage commenters to submit appropriate FDA documentation, published peer-reviewed literature, or other evidence-based support, if applicable, to illustrate why the commenters believe the drug, biological, or medical device meets the definition of a non-opioid treatment for pain relief. For these products, we also solicit comment on appropriate codes and descriptors if no HCPCS codes currently exist for the product. We note that we will evaluate these products, including the information submitted by commenters, and propose additional payments, subject to the payment limitation, for those that meet the definition of a non-opioid treatment for pain relief in the CY 2025 OPPS/ASC rulemaking cycle, rather than during the CY 2024 OPPS/ASC final rule with comment period.

b. Evidence Requirement for Medical Devices

Section 1833(t)(16)(G)(iv)(II)(bb) of the Act specifies an additional requirement for medical devices to meet the definition of non-opioid treatment for pain relief. This section requires that a medical device demonstrate the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal.

As the statute requires information from a clinical trial or data published in a peer-reviewed journal, we seek comment on the best way to obtain and evaluate that information. We also seek comment on how we should assess information from a clinical trial or data published in a peer-reviewed journal, including how to assess for conflicts of interest or integrity concerns, whether to focus on outcomes rather than surrogate endpoints, and whether to require that all decreases in opioid use be statistically and clinically significant compared to the usual standard of care (rather than placebo).

c. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act states that, subject to the limitation in clause (iii), the amount of payment for a non-opioid treatment for pain relief that is a drug or biological product is the amount of payment for such drug or biological determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(i) of the Act, we anticipate implementing a similar payment methodology for drugs and biologicals under this future policy.

Section 1833(t)(16)(G)(ii)(II) of the Act states that the amount of payment for a non-opioid treatment for pain relief that is a medical device is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the device. As this language is very similar to the transitional pass-through language at section 1833(t)(6)(D)(ii) of the Act, we anticipate implementing a similar payment methodology for medical devices under this future policy.

Section 1833(i)(10) of the Act provides that the same payment rate shall apply in the ASC setting as the rates described in section 1833(t)(16)(G)(ii) of the Act for hospital outpatient departments, subject to the limitation in section 1833(t)(16)(G)(iii) of the Act.

d. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the additional payment amount specified in clause (ii), and as described in the previous section, shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary. We are seeking comment on how we should determine the OPD service or groups of services with which non-opioid treatments for pain relief are furnished for purposes of calculating the payment limitation for each treatment. Specifically, we seek comment on the scenarios outlined below.

Additionally, we welcome other recommendations from interested parties consistent with the statutory requirements.

Scenario 1: Payment Limitation Based on the Top Five Services by Volume With Known Claims Data

As demonstrated in this example (Table 64), one possible approach is to use the top five services associated with a hypothetical drug, biological, or medical device, to determine the volume-weighted payment rate and the payment limit, based on the most recent claims data available. For the non-opioids that are currently separately paid, we predict that the majority of utilization is focused in the top five mostly frequently performed services, thus using the top five services would provide a representative estimate for the payment limit. However, we solicit comment on this prediction and welcome input from commenters if they believe another number of procedures, or another metric, would be appropriate to determine the list of procedures in which the payment limitation would be calculated.

For this example, we would begin by identifying the top five services by volume that package this drug, biological, or device into their payment rate. Second, we would calculate the volume-weighted payment rate per claim, which would be $700 in the example below. Third, we would apply the 18 percent payment limit per clinical dose, rather than per HCPCS dosage unit, which is $126 in the case below. We would apply this payment limit to the clinical dose received by the beneficiary as the payment limit applies to the total amount of payment, rather than the HCPCS dosage unit payment, which may only represent a small fraction of the total amount of payment. This means that even if the non-opioid treatment for pain relief had an amount of additional payment under section 1833(t)(16)(G)(ii) of the Act that was greater than $126 per dose, it would be limited to $126 by 1833(t)(16)(G)(iii) of the Act. In this example, this non-opioid treatment for pain relief would not be subject to the threshold packaging policy in section V.B.1.a. of this proposed rule even though its payment falls below the proposed CY 2024 drug packaging threshold of $140, per section 1833(t)(16)(G)(i) of the Act, and would also be separately paid when used during a comprehensive APC (C–APC) procedure in the HOPD setting.

TABLE 64: Example of Payment Limitation Based on the Top Five Services by Volume

Service	Volume (claims)	Payment	Total Payment (volume * claims)	Volume Weighted Payment per claim (total payment / total volume)	Payment Limit
1	100	1000	100,000	$\frac{(100{,}000 + 4{,}000 + 1{,}000 + 1{,}000 + 1{,}000)}{100 + 20 + 10 + 10 + 10}$ = $700	$700 * 0.18 = $126
2	20	200	4,000		
3	10	100	1,000		
4	10	100	1,000		
5	10	100	1,000		

We welcome comments on this approach. We seek comment on whether utilizing the top five services by volume is an appropriate method by which to establish this payment limit. We also seek comment on additional methodologies, such as determining the payment limit based on the top 10 services by volume, by total payment rather than volume, or any number of services with more than a certain percentage of overall utilization, such as 10 percent.

Scenario 2: Payment Limit Without Claims Data

Additionally, we seek comment on the best approach for determining a payment limit, pursuant to section 1833(t)(16)(G)(iii) of the Act for drugs, biologicals, and devices when there are no known claims data, such as for newly FDA-approved and marketed products. CMS could propose the services with which a product would be expected to be furnished and would typically be packaged absent this policy during calendar year rulemaking, based on expected clinical use patterns. Determining the service, or group of services, to use to calculate the payment limit could be accomplished through engagement with interested parties and a review by CMS Medical Officers and clinical staff. Absent engagement from interested parties, CMS could make its determination of the service, or group of services, to use to calculate the payment limit based on expected clinical use patterns. CMS could then adjust the services that are used to calculate the payment limit as claims data becomes available in subsequent years. We seek comment on this approach as well as other approaches of interest to commenters.

We welcome comment from interested parties on the implementation of all facets of section 4135. We will include proposals to implement the section 4135 amendments in the CY 2025 OPPS/ASC proposed rule.

G. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

- Applicants submit their NTIOL requests for review to CMS by the annual deadline. For a request to be considered complete, we require submission of the information requested in the guidance document titled ''Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class'' posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/NTIOLs.html*.
- We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Public Law 103–432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests in the proposed rule.
- In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests To Establish New NTIOL Classes for CY 2024

We did not receive any requests for review to establish a new NTIOL class for CY 2024 by March 1, 2023, the due date published in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72091).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2024.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007 ASC final rule (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

We note that we consider the term ''expenditures'' in the context of the budget neutrality requirement under section 1833(i)(2)(D)(ii) of the Act to mean expenditures from the Medicare Part B Trust Fund. We do not consider expenditures to include beneficiary coinsurance and copayments. This distinction was important for the CY 2008 ASC budget neutrality model that considered payments across the OPPS, ASC, and MPFS payment systems. However, because coinsurance is almost always 20 percent for ASC services, this interpretation of expenditures has minimal impact for subsequent budget neutrality adjustments calculated within the revised ASC payment system.

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007 ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2 of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes results in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the unadjusted hospital wage indexes, which are updated yearly and are used by many other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs. Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246 through 37252) and 2010 Census Bureau data. (A copy of this bulletin may be obtained at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2013/b13-01.pdf.*) In the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963), we implemented the use of the CBSA delineations issued by OMB in OMB Bulletin 13–01 for the IPPS hospital wage index beginning in FY 2015.

OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. OMB Bulletin No. 15–01 made changes that are relevant to the IPPS and ASC wage index. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79750) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2015/15-01.pdf.*)

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. We refer readers to the

CY 2019 OPPS/ASC final rule with comment period (83 FR 58864 through 58865) for a discussion of these changes and our implementation of these revisions. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/bulletins/2017/b-17-01.pdf*.)

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. A copy of OMB Bulletin No. 18–03 may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/04/OMB-BULLETIN-NO.-18-03-Final.pdf*. A copy of OMB Bulletin No. 18–04 may be obtained at *https://www.whitehouse.gov/wpcontent/uploads/2018/90/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*.)

The proposed CY 2024 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed above, as set forth in OMB Bulletin Nos. 13–01, 15–01, 17–01, 18–03, 18–04, and 20–01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. For these areas, our policy has been to use the average of the wage indexes for CBSAs (or metropolitan divisions as applicable) that are contiguous to the area that has no wage index (where ''contiguous'' is defined as sharing a border). For example, for CY 2024, we are applying a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville-Fort Stewart, GA).

When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, we determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2024 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

Where the estimated ASC expenditures for an upcoming year are higher than the estimated ASC expenditures for the current year, the ASC weight scalar is reduced, in order to bring the estimated ASC expenditures in line with the expenditures for the baseline year. This frequently results in ASC relative payment weights for surgical procedures that are lower than the OPPS relative payment weights for the same procedures for the upcoming year. Therefore, over time, even if procedures performed in the HOPD and ASC receive the same update factor under the OPPS and ASC payment system, payment rates under the ASC payment system would increase at a lower rate than payment for the same procedures performed in the HOPD as a result of applying the ASC weight scalar to ensure budget neutrality.

As discussed in section II.A.1.a of this proposed rule, we are using the CY 2022 claims data to be consistent with the OPPS claims data for this proposed rule. Consistent with our established policy, we propose to scale the CY 2024 relative payment weights for ASCs according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2022, we propose to compare the estimated total payment using the CY 2023 ASC relative payment weights with the estimated total payment using the CY 2024 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2023 and CY 2024.

Additionally, in light of our policy to provide a higher ASC payment rate through the use of ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporate estimated total spending and estimated utilization for these codes in our budget neutrality calculation. We estimated in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72094) that the impact on CY 2023 estimated total payments from our proposed CY 2023 ASC complexity adjustment codes would be $5 million in spending and we propose to incorporate this $5 million in estimated CY 2023 total payments for the budget neutrality calculation of this proposed rule. For estimated CY 2024 total payments, we propose to incorporate the estimated total spending and estimated utilization related to our proposed CY 2024 ASC complexity adjustment codes. In this proposed rule, we estimate the additional CY 2024 spending related to our proposed ASC complexity adjustment codes will be $5 million.

We propose to use the ratio of estimated CY 2023 to estimated CY 2024 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2024. The proposed CY 2024 ASC weight scalar is 0.8649. Consistent with historical practice, we propose to scale, using this method, the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We propose that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those

services. The ASC payment weights for those services without predetermined national payment amounts (that is, those services with national payment amounts that would be based on OPPS relative payment weights) would be scaled to eliminate any difference in the total payment between the current year and the update year.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2022 claims data to model our budget neutrality adjustment for CY 2024.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor. For CY 2024, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2022 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2024 ASC wage indexes. Specifically, holding CY 2022 ASC utilization, service-mix, and the proposed CY 2024 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2023 ASC wage indexes and the total adjusted payment using the proposed CY 2024 ASC wage indexes. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2023 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2024 ASC wage indexes and applied the resulting ratio of 1.0017 (the proposed CY 2024 ASC wage index budget neutrality adjustment) to the CY 2023 ASC conversion factor to calculate the proposed CY 2024 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act 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). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2024 was projected to be 0.2 percentage point, as published in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005) based on IGI's 2022 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI–U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI–U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii), to update the ASC conversion factor using the CPI–U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the productivity-adjusted hospital market basket update to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there is a migration of the performance of procedures from the hospital setting to the ASC setting as a result of the use of a productivity-adjusted hospital market basket update, as well as whether there are any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. The most recent available full year of claims data to assess the expected migration applying the hospital market basket update during the interim period would fall within the period from CY 2019 through CY 2022. However, the impact of the COVID–19 PHE on health care utilization, in particular in CY 2020, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings when possible to avoid possible infection from the SARS–CoV–2 virus. As a result, it is nearly impossible to disentangle the effects from the COVID–19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we need to use claims data from a period during which the COVID–19 PHE had less of an impact on health care utilization. Therefore, for this CY 2024 OPPS/ASC proposed rule, we propose to extend the 5-year interim period an additional 2 years, that is, through CY 2024 and CY 2025. We believe hospital outpatient and ASC utilization data from CYs 2023 and 2024 will enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We propose to revise our regulations at 42 CFR 416.171(a)(2)(iii) and (iv), which establish the annual update to the ASC conversion factor, to reflect this 2-year extension. We also propose to revise our regulations at § 416.171(a)(2)(vi) and (vii), which establish the 2.0 percentage point reduction for ASCs that fail to meet the standards for reporting ASC quality measures, and § 416.171(a)(2)(viii)(B) and (C), which establish the productivity adjustment, to reflect this 2-year extension.

For CY 2024, in accordance with our proposed revisions to § 416.171(a)(2)(iii), (vi), and (viii)(B), we propose to utilize the hospital market basket update of 3.0 percent reduced by the productivity adjustment of 0.2 percentage point, resulting in a proposed productivity-adjusted hospital market basket update factor of 2.8 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a 2.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2024 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the update factor for ASCs that fail to meet the ASCQR Program requirements. We refer readers to section XIV.E of the CY 2019 OPPS/ASC final rule with

comment period (83 FR 59138 through 59139) and section XIV.E of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the inpatient hospital market basket percentage increase of 3.0 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the 0.2 percentage point productivity adjustment. Therefore, we propose to apply a 0.8 percent productivity-adjusted hospital market basket update factor to the CY 2023 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2024 ASC update for the CY 2024 OPPS/ASC final rule with comment period.

For CY 2024, we propose to adjust the CY 2023 ASC conversion factor ($51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the productivity-adjusted hospital market basket update of 2.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of $53.397 for ASCs meeting the quality reporting requirements. For ASCs not meeting the quality reporting requirements, we propose to adjust the CY 2023 ASC conversion factor ($51.854) by the proposed wage index budget neutrality factor of 1.0017 in addition to the quality reporting/productivity-adjusted hospital market basket update of 0.8 percent discussed above, which results in a proposed CY 2024 ASC conversion factor of $52.358.

3. Display of the Proposed CY 2024 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2024 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC proposed payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2024 payment rates. Specifically, in Addendum AA, a ''Y'' in the column titled ''To be Subject to Multiple Procedure Discounting'' indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

For CY 2021, we finalized adding a new column to ASC Addendum BB titled ''Drug Pass-Through Expiration during Calendar Year'' where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that is, on a date other than December 31st).

The values displayed in the column titled ''Proposed CY 2024 Payment Weight'' are the proposed relative payment weights for each of the listed services for CY 2024. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2024 payment rate displayed in the ''Proposed CY 2024 Payment Rate'' column, each ASC payment weight in the ''Proposed CY 2024 Payment Weight'' column was multiplied by the proposed CY 2024 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update factor as reduced by the productivity adjustment. The proposed CY 2024 ASC conversion factor uses the CY 2024 productivity-adjusted hospital market basket update factor of 2.8 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by the proposed productivity adjustment of 0.2 percentage point).

In Addendum BB, there are no relative payment weights displayed in the ''Proposed CY 2024 Payment Weight'' column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The ''Proposed CY 2024 Payment'' column displays the proposed CY 2024 national unadjusted ASC payment rates for all items and services. The proposed CY 2024 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on the most recently available data used for payment in physicians' offices.

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are finalized to be excluded from payment in ASCs for CY 2024.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2024 for covered surgical procedures.

XIV. Hospital Outpatient Quality Reporting (OQR) Program Requirements, Proposals, and Requests for Comment

A. Background

We seek to promote higher quality, more efficient, and equitable healthcare for patients. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Hospital Outpatient Quality Reporting (OQR) Program for hospital outpatient care.

We refer readers to the CY 2011 Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) payment system final rule (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. We refer readers to the CYs 2008 through 2023 OPPS/ASC final rules for detailed discussions of the regulatory history of the Hospital OQR Program (72 FR 66860 through 66875; 73 FR 68758 through 68779; 74 FR 60629 through 60656; 75 FR 72064 through 72110; 76 FR 74451 through 74492; 77 FR 68467 through 68492; 78 FR 75090 through 75120; 79 FR 66940 through 66966; 80 FR 70502 through 70526; 81 FR 79753 through 79797; 82 FR 59424 through 59445; 83 FR 59080 through 59110; 84 FR 61410 through 61420; 85 FR 86179 through 86187; 86 FR 63822 through 63875; and 87 FR 72096 through 72117).

We have codified certain requirements under the Hospital OQR Program at 42 CFR 419.46. We refer readers to section XIV.F of this proposed rule for a detailed discussion

of the payment reduction for hospitals that fail to meet Hospital OQR Program requirements.

B. Hospital OQR Program Quality Measures

1. Retention, Removal, Replacement, or Suspension of Quality Measures From the Hospital OQR Program Measure Set

We refer readers to § 419.46(i) for our policies regarding: (1) measure retention; (2) immediate measure removal; and (3) measure removal, suspension, or replacement through the rulemaking process. We propose to amend our immediate measure removal policy codified at § 419.46(i)(2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

a. Proposed Removal of the Left Without Being Seen Measure Beginning With the CY 2024 Hospital OQR Reporting Period

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72088 through 72089) where we adopted the Left Without Being Seen (LWBS) measure beginning with the CY 2013 payment determination. The LWBS measure was initially endorsed by a consensus-based entity (CBE) in 2008. This process measure assesses the percent of patients who leave the emergency department (ED) without being evaluated by a physician, advanced practice nurse, or physician's assistant. Our rationale for adopting the LWBS measure was that patients leaving without being seen was an indicator of ED overcrowding (75 FR 72089).

Endorsement of the measure was removed in 2012 because the measure steward did not choose to resubmit the measure to maintain endorsement. We continued to retain the LWBS measure because our data showed variation/gap in performance and improvement. However, over the last few years, our routine measure monitoring and evaluation indicated: (1) limited evidence linking the measure to improved patient outcomes; (2) that increased LWBS rates may reflect poor access to timely clinic-based care rather than intrinsic systemic issues within the ED; [137] and (3) unintended effects on LWBS rates caused by other policies, programs, and initiatives may lead to skewed measure performance.[138] [139] [140]

We recognize that LWBS performance issues could be due to inefficient patient flow in the ED for a variety of reasons or due to insufficient community resources, which result in higher ED patient volumes that lead to long wait times and patients deciding to leave without being seen. These patients' reasoning for visiting the ED is often not severe enough that they would want to wait if the ED is crowded. Additionally, we do not believe that the LWBS measure provides enough specificity to give value because it does not provide granularity for actionable meaningful data toward quality improvement.

We believe, based on these findings, that this measure meets the measure removal factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B).

ED performance and care continues to be an important topic area of the Hospital OQR Program. We believe the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure (Median Time for Discharged ED Patients measure) is better for measuring ED performance and care. The Median Time for Discharged ED Patients measure, adopted for reporting in the Hospital OQR Program, provides more meaningful data compared to the LWBS measure because the measure presents more granular data on length of time of ED throughput. Additionally, the Median Time for Discharged ED Patients measure provides useful information to facilities for improvement efforts because the measure is stratified, showing the median time from ED departure for discharged ED patients in four different strata in the Hospital Outpatient Department (HOPD) setting. These improvement efforts by facilities could ultimately reduce the number of patients who leave without being seen.

Based on the above assessment and rationale, we believe the LWBS measure does not provide enough evidence to promote quality of care and improved patient outcomes to justify retaining the measure in the Hospital OQR Program. Therefore, we propose to remove the LWBS measure from the program beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on our proposal.

2. Modifications to Previously Adopted Measures

In this proposed rule, we propose to modify three previously adopted measures beginning with CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure; and (3) Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure.

a. Proposed Modification of the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a then novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[141] Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs, including the Hospital OQR Program (86 FR 63824 through 63833).[142] COVID–19 has continued to spread domestically and around the world with more than 102.7 million cases and 1.1 million deaths in the United States alone as of February

[137] Li DR, Brennan JJ, Kreshak AA, et al. (2019). Patients who leave the emergency department without being seen and their follow-up behavior: a retrospective descriptive analysis. *J Emerg Med*, 57(1), 106–13. *https://doi.org/10.1016/j.jemermed.2019.03.051.*

[138] Allen L, Cong TG, & Kosali S. (2022). The Impact of Medicaid Expansion on Emergency Department Wait Times. *Health Services Research*, 57(2), 294–99. *https://doi.org/10.1111/1475-6773.13892.*

[139] Roby N, Smith H, Hurdelbrink J, et al. (2022). Characteristics and Retention of Emergency Department Patients Who Left without Being Seen (LWBS). *Internal and Emergency Medicine,* 17(2), 551–58. *https://doi.org/10.1007/S11739-021-02775-Z.*

[140] Yoo MJ, Schauer SG, & Trueblood WE. (2022). 'Swab and Go' Impact on Emergency Department Left without Being Seen Rates.'' *The American Journal of Emergency Medicine*, 57(July): 164–65. *https://doi.org/10.1016/J.AJEM.2021.11.043.*

[141] 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*

[142] The ASCQR Program (86 FR 63875 through 63833), the Hospital IQR Program (86 FR 45374 through 45382), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), 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), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

13, 2023.[143] The Secretary renewed the PHE on April 21, 2020, and then every three months thereafter, with the final renewal on February 9, 2023.[144] The PHE expired on May 11, 2023; however, the public health response to COVID–19 remains a public health priority including vaccination efforts.[145]

We stated in the CY 2022 OPPS/ASC final rule (86 FR 63825), and in our ''Revised Guidance for Staff Vaccination Requirements,'' that vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19.[146] [147] [148] We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the HOPD setting, 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. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID–19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[149] Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[150] [151] [152] [153] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death from COVID–19 infection.[154]

When we adopted the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we acknowledged that the measure did not address booster shots for COVID–19 vaccination (86 FR 63881) though the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended, additional doses and booster doses of the COVID–19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in high-risk settings, such as HCP (86 FR 63881). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' (86 FR 63881).

Since then, 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.[155] 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.[156] Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing 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.[157] These booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[158] [159] [160] Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across HOPDs.

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, 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 for HCP

[143] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home.*

[144] 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.*

[145] 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.*

[146] Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[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://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.*

[148] Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[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 at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm.*

[150] Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*, 385(25), e90. *https://doi.org/10.1056/NEJMoa2106599.*

[151] Centers for Disease Control and Prevention. (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.*

[152] Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[153] Food and Drug Administration. (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.*

[154] McGarry BE, Barnett ML, Grabowski DC, et al. (2022). Nursing Home Staff Vaccination and Covid–19 Outcomes. *New England Journal of Medicine*, 386(4), 397–398. *https://doi.org/10.1056/NEJMc2115674.*

[155] Centers for Disease Control and Prevention. (2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html.*

[156] Food and Drug Administration. (2022). COVID–19 Bivalent Vaccine Boosters. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines.*

[157] Chalkias S, Harper C, Vrbicky K, et al. (2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. *New England Journal of Medicine*, 387(14), 1279–1291. *https://doi.org/10.1056/NEJMoa2208343.*

[158] Prasad N, Derado G, Nanduri SA, 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). 71(18), 633–637. Available online at: *https://www.cdc.gov/mmwr/volumes/71/wr/mm7118a4.htm.*

[159] Oster Y, Benenson S, Nir-Paz R, et al. (2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. *Clinical Microbiology and Infection*, 28(5), 735.e1–735.e3. *https://doi.org/10.1016/j.cmi.2022.01.019.*

[160] Ibid.

to receive primary series and booster vaccine doses in a timely manner per CDC's recommendation that bivalent COVID–19 vaccine booster doses might improve protection against SARS–CoV–2 Omicron sublineages.[161]

We propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition. We also propose to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including booster doses, beginning with CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program.

We note that as we stated in the CY 2022 OPPS/ASC final rule (86 FR 63877), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates and not an outcome measure for which hospitals are held responsible for a particular outcome. We propose to adopt the same modification to versions of the measure that we have adopted for other quality reporting programs.[162]

(2) Overview of Measure

The COVID–19 Vaccination Coverage Among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCPs in various settings and are reported via the CDC's National Healthcare Safety Network (NHSN). We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63827 through 63828) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).[163] 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, during the MAP's Hospital Workgroup discussion, the workgroup stated that the revision of the current measure captures up to date vaccination information in accordance with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup appreciated that the re-specified measure's target population is broader and simplified from seven categories of HCP to four.[164] During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID–19 vaccination measures and questioned whether the proposed revised measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator but stated that 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.[165] We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation.

The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431).[166] We refer readers to sections XXIV.B and XXVI of this proposed rule for additional detail on the burden and impact of this proposal.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the CBE. The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636)[167] and that the measure steward (CDC) intends to submit the updated measure for endorsement.[168]

(a) Measure Specifications

This measure is calculated quarterly by averaging the hospital's most recently submitted and self-selected 1 week of data. The measure includes at least 1 week of data collection a month for each of the 3 months in a quarter. The denominator is calculated as the aggregated number of HCP eligible to work in the hospital for at least 1 day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all 3 months in a quarter.[169] Facilities report the following four categories of HCP to the NHSN:

- *Employees:* This 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.)
- *Licensed independent practitioners (LIPs):* This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility but are not directly employed by it (that is, they do not receive a 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.
- *Adult students/trainees and volunteers:* This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the facility but are not directly employed by it (that is, they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
- *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

[161] Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[162] The Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074) as well as the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

[163] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[164] Centers for Medicare & Medicaid Services. Pre-rulemaking MUC lists and map reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[165] Ibid.

[166] In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

[167] Centers for Medicare and Medicaid Services. Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670&sectionNumber=1.*

[168] The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare and Medicaid Services (2023). Roles in Measure Development. Available at: *https://mmshub.cms.gov/about-quality/new-to-measures/roles.*

[169] 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.*

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 HCP COVID–19 Vaccine measure.[170]

We are not proposing to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccine. Guidance issued by the CDC defines the term ''up to date'' as meeting the CDC's criteria on the first day of the applicable reporting quarter. The current definition of ''up to date'' can be found at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.*

We propose that public reporting of the modified version of the COVID–19 Vaccination Coverage Among HCP for the Hospital OQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

(b) CBE Endorsement

The current version of the measure in the Hospital OQR Program received CBE endorsement (CBE #3636) on July 26, 2022.[171] The measure steward (CDC) is pursuing endorsement for the modified version of this measure.

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63879 through 63883) for information on data submission and reporting of this measure. While we are not proposing any changes to the data submission or reporting process, we propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the Hospital OQR Program. Under the data submission and reporting process, hospitals would collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet Hospital OQR Program requirements. If a hospital submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, the third week data would be used. Each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each hospital, which would be calculated by taking the average of the data from the three weekly rates submitted by the hospital for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878). We refer readers to section XV.B of this proposed rule for the same proposal for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program.

We invite public comment on this proposal.

b. Proposed Modification of Survey Instrument Use for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPS/ASC final rule (78 FR 75102 through 75103), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (the Cataracts Visual Function) measure, beginning with the CY 2014 reporting period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75102). A ''survey instrument'' is an assessment tool that has been appropriately validated for the population for which it being used.[172] For purposes of this proposed modification to the Cataracts Visual Function measure, the survey instruments we considered and propose assess the visual function of a patient pre- and post-operatively to determine whether the patient's visual function changed within 90 days of cataract surgery. Currently, examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI–VFQ), the Visual Function (VF–14), the modified (VF–8), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest–9. While the measure has been available for voluntary reporting in the Hospital OQR Program since the CY 2015 reporting period, a number of facilities have reported data consistently using the survey instrument-collection method of their choice (87 FR 72098). We refer readers to the Cataracts Visual Function measure's Measure Information Form (MIF) and the Hospital OQR Program Specifications Manual for additional detail, which is available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*.

In the CY 2015 OPPS/ASC final rule (79 FR 66947), we expressed concerns that clinicians' use of varying survey instruments would lead to inconsistent measure results. However, a comparison study conducted of the 16 survey instruments that are currently accepted for use in collecting data for this measure by HOPDs found them to be scientifically valid, able to detect clinically important changes, and provide comparable results.[173] While all 16 survey instruments demonstrate usefulness for detecting clinically important changes in cataract patients, some survey instrument's detection sensitivity scored higher than others.[174]

Several commenters responding to the CY 2022 OPPS/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments. We agree that the use of survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified. The use of survey instruments should be standardized across HOPDs to minimize collection and reporting burden, as well as to improve measure reliability. We propose to clarify which specific survey instruments may be used for the assessment of visual function pre- and post- cataract surgery for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. Thus, we propose to limit the allowable survey instruments that an HOPD may use to assess changes in patient's visual function for the purposes of the Cataracts Visual Function measure to those listed below:

[170] 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.*

[171] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[172] Centers for Medicare & Medicaid Services. (2023). Hospital OQR Specification Manual Version 16.0. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab1.*

[173] McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology*, 118(12), 2374–81. *https://doi.org/10.1016/j.ophtha.2011.06.008.*

[174] Ibid.

The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ–25)
The Visual Functioning Patient Questionnaire (VF–14)
The Visual Functioning Index Patient Questionnaire (VF–8R)

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We took into consideration several factors when identifying which specific survey instruments would be acceptable for HOPDs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We believe that these three proposed survey instruments will allow HOPDs to select the length of the survey to be administered while ensuring adequate validity and reliability.[175] [176] [177] All three of these proposed surveys are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ–51) survey instrument, which was the first survey instrument originally developed for assessing a patient's visual function before and after cataract surgery. Each of the three proposed survey instruments have progressively fewer numbers of questions than the NEI VFQ–51: 25 questions for the NEI VFQ–25, 14 questions for the VF–14, and 8 questions for the VF–8R. Even with fewer numbers of questions, all three of the proposed survey instruments have been validated as providing results comparable to the NEI VFQ–51. In addition, all three of the proposed survey instruments are readily available for hospitals to access and use.

We propose to allow HOPDs to use the NEI VFQ–25 for administering and calculating the Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ–25 is a shorter version of the NEI VFQ–51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).[178]

The NEI VFQ–25, similar to the VF–14 and VF–8R, displays adequate reliability and validity.[179] The NEI VFQ–25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity.[180] Furthermore, the NEI VFQ–25's high internal consistency, indicates that items of the NEI VFQ–25 are highly related to each other and to the scale as a whole.[181]

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ–25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.[182] More information on the NEI VFQ–25 can be found at: *https://www.rand.org/health-care/surveys_tools/vfq.html*.

While the NEI VFQ–25 was shortened significantly from the original NEI VFQ–51, it has been criticized for its still lengthy test-time. However, our proposal to include this survey instrument in this measure's specifications allows for a more detailed assessment of cataract surgery outcomes, as it was designed to include questions which are most important for persons who have chronic eye diseases.[183] Further, if a hospital finds the NEI VFQ–25 particularly burdensome to administer, the hospital may choose from the other two survey instruments we propose for inclusion in this measure's specifications, as both of these have even fewer survey questions to administer.

We also propose to allow HOPDs to use the 14-item VF–14 and the 8-item VF–8R for administering and calculating the Cataracts Visual Function measure, which each can be administered in a shorter timeframe than the NEI VFQ–25 with high precision.[184] [185] Thus, the succinct formats of the VF–14 and VF–8R may ease HOPD's burden in administering the survey instruments and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. Therefore, we propose the VF–14 and VF–8R for this measure's data collection specifications because we believe these survey instruments achieve comparable results with the longer NEI VFQ–25 and NEI VFQ–51 survey instruments with substantially fewer questions to administer.

Furthermore, we propose inclusion of the VF–14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using VF–14 to continue to have the option to do so.[186] The VF–14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.[187] Studies using this survey instrument generally report significant and clinically important improvement following cataract surgery.[188] The VF–14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.[189] [190]

[175] Sivaprasad S., Tschosik E., Kapre A., et al. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006*.

[176] Hecht I., Kanclerz P., & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity''. *Progress in Retinal and Eye Research*, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

[177] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. Mdinteractive. Available at: *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[178] U.S. Department of Health and Human Services. *Visual function questionnaire 25*. National Eye Institute. Available at: *https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25*.

[179] Sivaprasad S., Tschosik E., Kapre A., et al. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. *American Journal of Ophthalmology*, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006*.

[180] Ibid.

[181] Ibid.

[182] Mangione C.M., Phillips R.S., Seddon J.M., et al. (1992). Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. *Med Care*, 30(12), 1111–1126. *https://doi.org/10.1097/00005650-199212000-00004*.

[183] Hecht I., Kanclerz P., & Tuuminen R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

[184] Ibid.

[185] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Available at: *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[186] Hecht, I., Kanclerz, P., &; Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

[187] Ibid.

[188] Ibid.

[189] Ibid.

[190] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

We propose the VF–8R as it is the most concise of the three survey instruments, while still achieving adequate validity and reliability.[191] The VF–8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.[192] Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we believe that the VF–8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.[193]

For these reasons, we believe that the NEI VFQ–25, VF–14, and VF–8R are the most appropriate survey instruments for HOPDs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the Hospital OQR Program.

In response to commenters' concerns as summarized in the CY 2023 OPPS/ASC final rule (87 FR 72097 through 72099) regarding the lack of specificity around survey instrument administration for the Cataracts Visual Function measure, we propose to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ–25; (2) VF–14; and (3) VF–8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure would allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address commenters' requests for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPS/ASC final rule (87 FR 72104 through 72105), many commenters expressed concern about the high administrative burden of reporting the Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient's physician or optometrist administer, collect, and report the survey instrument results to the HOPD, the survey instruments required for this measure can be administered by the HOPD itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.[194] [195] Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to surveys in their preferred format.[196] [197] These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invite public comment on this proposal.

c. Proposed Modification of the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change To Align With Current Clinical Guidelines Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and the 4th highest rate of cancer deaths in the United States.[198] The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.[199] The CDC advises, ''[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [200]

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.[201] This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[202] In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.[203] [204] [205] Based on the recent changes in clinical guidelines

[191] Ibid.

[192] Pre-Cataract Surgery—Visual Functioning Index (VF–8R) patient. (n.d.). *https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf.*

[193] Ibid.

[194] Bhandari N.R., Kathe N., Hayes C., & Payakachat N. (2018). Reliability and validity of SF–12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy, 14*(11), 1080–1084. *https://doi.org/10.1016/j.sapharm.2018.01.007.*

[195] Stolwijk C., van Tubergen A., Ramiro S., et al. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology, 53*(6), 1054–1064. *https://doi.org/10.1093/rheumatology/ket354.*

[196] Kelfve S., Kivi M., Johansson B., & Lindwall M. (2020). Going web or staying paper? the use of web-surveys among older people. BMC Medical Research Methodology, 20(1), 252. *https://doi.org/10.1186/s12874-020-01138-0.*

[197] Meyer V.M., Benjamens S., Moumni M.E., et al. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery, 275*(1). *https://doi.org/10.1097/sla.0000000000004078.*

[198] Centers for Disease Control and Prevention. (2022). Colorectal Cancer Statistics. Available at: *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/.*

[199] American Cancer Society. (2023). Cancer Facts & Figures 2023. Available at: *https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html.*

[200] Centers for Disease Control and Prevention. (2022). What Should I Know About Screening? Available at: *https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm.*

[201] US Preventive Services Task Force. (2021). Screening for Colorectal Cancer. *JAMA*, 325(19), 1965–1977. *https://doi.org/10.1001/jama.2021.6238.*

[202] Ibid.

[203] Wolf A., Fontham E.T.H., Church T.R., et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.*, 2018(68), 250–281. *https://doi.org/10.3322/caac.21457.*

[204] American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: *https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom.*

[205] Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology*, 117(1), 57–69. *https://doi.org/10.14309/ajg.0000000000001548.*

to begin CRC screening at age 45 instead of age 50, we propose to modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the Colonoscopy Follow-Up Interval) measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool and the Hospital OQR Program specification manual for more information on the Colonoscopy Follow-Up Interval measure, including background on the measure and a complete summary of measure specifications.[206] [207] Currently, the Colonoscopy Follow-Up Interval measure assesses the ''percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' [208] We propose to amend the measure's denominator language by replacing the phrase ''aged 50 years'' with the phrase ''aged 45 years.'' The measure denominator would be modified to ''all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy'' from ''all patients aged *50 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy.'' [209] We are not proposing any changes to the measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure (which we propose here for the Hospital OQR Program) for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines. As a result, we propose to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the Hospital OQR Program. We propose the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on this proposal.

3. Proposed Adoption of New Measures for the Hospital OQR Program Measure Set

Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking, the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment (75 FR 72064).

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act. We followed this pre-rulemaking process for the measures we propose for adoption for the Hospital OQR Program under this section of the proposed rule, as further detailed below.

In this proposed rule, we propose to: (1) re-adopt the original Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (2) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM), beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; and (3) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults measure, beginning with the voluntary CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In this section of the proposed rule, we provide additional information on these measure adoption proposals.

a. Proposed Re-Adoption With Modification of the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures Measure Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.[210] Research indicates that volume of services performed in HOPDs will continue to grow, with some estimates projecting a 19 percent increase in patients between 2019 and 2029.[211] In light of this trend, it has become even more important to track volume within HOPDs. Larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient team work and increased surgical experience, discussed in more detail below.[212] Given the association between volume and outcomes, this information could provide valuable insight to patients when choosing a HOPD.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring

[206] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1*.

[207] Centers for Medicare & Medicaid Services. Qualitynet Home. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*.

[208] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1*.

[209] Ibid.

[210] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf*.

[211] Sg2. (2021). Sg2 Impact of Change Forecast Predicts Enormous Disruption in Health Care Provider Landscape by 2029. Available at: *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/*.

[212] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155*.

outcomes.[213] However, experts on quality and safety have recently suggested that while volume alone may not indicate or lead to better outcomes, it is still an important component of quality.[214] [215] [216] Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.[217] For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.[218] This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The Hospital OQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but it did so previously. We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74466 through 74468) where we adopted the Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures (HOPD Procedure Volume) measure beginning with the CY 2014 payment determination. This structural measure of facility capacity collected surgical procedure volume data on nine categories of procedures frequently performed in the hospital outpatient setting: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, Skin, and Other.[219] We adopted the HOPD Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased mortality (76 FR 74466).[220] [221] We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74467).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59429 through 59430), we removed the HOPD Procedure Volume measure, stating our belief at that time that there is a lack of evidence to support this specific measure's link to improved clinical quality. Although there is currently increased evidence of a link between patient volume and better patient outcomes, we previously stated that we believed that there was a lack of evidence that this link was reflected in the HOPD Procedure Volume measure. At the time, we stated that measuring the number of surgical procedures does not offer insight into the facilities' overall performance or quality improvement in regard to surgical procedures (82 FR 59429). Thus, we removed the HOPD Procedure Volume measure beginning with the CY 2020 payment determination based on measure removal factor 2 (that is, performance or improvement on a measure does not result in better patient outcomes), as codified under § 419.46(i)(3)(i)(B).

In the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), we stated that we have been considering re-adopting the HOPD Procedure Volume measure with modification for two reasons. First, since the removal of the HOPD Procedure Volume measure, scientific literature has concluded that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[222] Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume–mortality relationship related to transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.[223] Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including HOPDs. Given these developments, we believe that patients may benefit from the public reporting of facility-level volume measure data that reflect the procedures performed across hospitals, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures.

In response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), regarding the potential re-adoption of the Hospital Outpatient Surgical measure, several commenters expressed concern that the burden of collecting and reporting data for the measure outweighs its value (87 FR 72104 through 72105). Before its removal from the Hospital OQR Program, the HOPD Procedure Volume measure was the only measure that captured facility-level volume within HOPDs and volume for Medicare and non-Medicare patients. As a result, the Hospital OQR Program currently does not capture surgical procedure volume in HOPDs. We recognize that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims. However, the specifications for the HOPD Procedure Volume measure also include reporting data for non-Medicare patients; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of procedural volume.[224]

[213] Ibid.

[214] Ibid.

[215] Shang M, Mori M, Gan G, et al. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005–2016. The Journal of Thoracic and Cardiovascular Surgery, 164(6). *https://doi.org/10.1016/j.jtcvs.2020.11.098.*

[216] Iwatsuki M, Yamamoto H, Miyata H, et al. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer, 22*(1), 190–201. *https://doi.org/10.1007/s10120-018-0883-1.*

[217] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155.*

[218] Ibid.

[219] Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

[220] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). *https://doi.org/10.1161/jaha.121.023805.*

[221] Vemulapalli S, Carroll J, Mack, M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[222] Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[223] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109.*

[224] The specifications for the removed HOPD Procedure Volume measure are available in the Hospital Outpatient Specifications Manuals version 9.1 available at *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

In addition, in response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44730 through 44732), some commenters expressed their belief that volume is not a clear indicator of care quality and therefore procedure volume data would not be useful to consumers (87 FR 72104 through 72105). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.[225] [226] For example, studies published since the CY 2018 OPPS/ASC final rule found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[227] [228] We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities have experience with certain outpatient procedures and assist consumers in making informed decisions about where they receive care, acknowledging that many studies in recent years have shown that volume does serve as an indicator of quality of care.[229] [230]

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

The proposed HOPD Procedure Volume measure collects data regarding the aggregate count of selected surgical procedures. Most frequent outpatient procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[231] For this proposed measure, data surrounding the top five most frequently performed procedures among HOPDs in each category would be collected and publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.[232]

We propose that hospitals would submit aggregate-level data through the CMS Web-based tool (currently, the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74467). Data received through the HQR system would then be publicly displayed on Care Compare or another CMS website. We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures.

We propose to re-adopt the HOPD Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule, (76 FR 74468) we finalized that HOPDs would report all-patient volume data with respect to the eight categories mentioned prior. In response to commenter concerns regarding potential difficulty detecting procedural volume differentiation among these broad based categories (76 FR 74467), the sole modification to this measure is that instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among HOPDs within each category. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: *https://cmit.cms.gov/cmit/#/*.

We also propose that HOPDs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027 to May 15, 2027, covering the performance period of January 1, 2026 to December 31, 2026. We refer readers to section XIV.E.5 of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS Web-based tool. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the HOPD Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by the CBE.[233] The MAP acknowledged that the measure reports the volume of procedures performed at HOPDs in select categories reflecting typical high-volume categories of procedures and stated that the measure would capture the volume for many procedures not currently monitored by the Hospital OQR Program measure set. Furthermore, the MAP expressed its belief that measuring the volume of procedures would relate to the program's goals of improving the safety and quality of outpatient procedures in HOPDs.[234] The MAP added that electronic reporting of procedure volumes based on code lists should not be overly burdensome to hospitals, and the public reporting of specific procedure volumes may be useful to patients.[235]

The MAP described that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. One systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 included studies.[236] Furthermore, the MAP included a similar review in their analysis of the HOPD Procedure Volume measure that also focused on outpatient surgeries, which found a significant

[225] Ogola, GO, Crandall, ML, Richter, KM, & Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985*.

[226] Vemulapalli S, Carroll J, Mack M, et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine, 380*(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

[227] Mufarrih SH, Ghani MOA, Martins RS, et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. J Orthop Surg Res 14, 468. *https://doi.org/10.1186/s13018-019-1531-0*.

[228] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). *https://doi.org/10.1161/jaha.121.023805*.

[229] Ogola GO, Crandall ML, Richter KM, Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985*.

[230] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

[231] Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9*.

[232] Data source: Part A and B claims for Outpatient Hospitals for services January 1, 2022–December 31, 2022.

[233] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[234] Ibid.

[235] Ibid.

[236] Levaillant M, Marcilly R, Levaillant L, et al. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology*, 21(1). *https://doi.org/10.1186/s12874-021-01396-6*.

volume-outcome relationship across eight studies.[237]

The MAP stated that this measure addresses a national trend where even complex surgeries are moving from inpatient to outpatient settings, and that public reporting of this measure could help CMS and the public better understand possible quality differences between settings.[238] The MAP reported that the HOPD Procedure Volume measure data from 2015 and 2016 demonstrates that the number of procedures performed by facilities in the 25th and 75th percentiles varied across the condition categories.[239] These findings support our belief that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[240] [241]

In addition, the MAP noted the concurrent submission of MUC 2022–028: ASC Facility Volume Data on Selected Surgical Procedures for inclusion in the ASCQR Program. The MAP highlighted that the specifications of the volume measure proposal for the ASCQR Program are aligned with the volume measure we propose for the Hospital OQR Program and, therefore would facilitate comparisons of equivalent procedure volumes across ambulatory surgical centers (ASCs) and HOPDs, one of the key goals of the programs.[242]

(c) Measure Endorsement

As discussed in the previous subsection of the proposed rule, the MAP reviewed and conditionally supported the HOPD Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national consensus-based entity as the measure was not submitted for endorsement. As we noted in previous rulemaking (75 FR 72064), the requirement that measures reflect consensus among affected parties can be achieved in ways other than from endorsement by a national consensus-based entity, including the measure development process, broad acceptance of the measure(s), use of the measure(s), and public comment.

We considered the MAPs recommendation and propose to adopt the measure because we did not find any other measures of procedure volume. Additionally, this measure was previously in the program with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, we propose adoption of this measure in the Hospital OQR Program pending endorsement by a national consensus-based entity.

We invite public comment on this proposal.

b. Proposed Adoption of the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM) Beginning With Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we adopted the THA/TKA PRO–PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary FY 2025 and FY 2026 reporting periods, followed by mandatory reporting for eligible elective procedures occurring July 1, 2024 through June 30, 2025 for the FY 2028 payment determination. In this proposed rule, we propose the adoption of the THA/TKA PRO–PM into the Hospital OQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257), with modifications to include procedures performed in the HOPD setting.

Approximately six million adults aged 65 or older suffer from osteoarthritis in the United States.[243] In 2013, there were approximately 568,000 hospitalizations billed to Medicare for osteoarthritis.[244] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[245] [246] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[247] [248] Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[249] THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[250] [251] [252] However, not all

[237] Stanak M, & Strohmaier C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research*, 20(1). *https://doi.org/10.1186/s12913-020-05724-2.*

[238] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/.*

[239] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[240] Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985.*

[241] Saito Y, Tateishi K, Kanda M, et al. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association*, 11(6). *https://doi.org/10.1161/jaha.121.023805.*

[242] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[243] Arthritis Foundation. (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: *https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march2019.pdf.*

[244] Torio CM, & Moore BJ. (2016). National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK368492/.*

[245] Guccione AA, Felson DT, Anderson JJ, et al. (1994). The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *American journal of public health*, 84(3), 351–358. *https://doi.org/10.2105/AJPH.84.3.351.*

[246] Barbour KE, Helmick CG, Boring M, & Brady TJ. (2017). Vital Signs: Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation—United States, 2013–2015. *MMWR Morbidity and mortality weekly report*, 66(9), 246–253. *https://doi.org/10.15585/mmwr.mm6609e1.*

[247] Michaud CM, McKenna MT, Begg S, et al. (2006). The burden of disease and injury in the United States 1996. *Population health metrics*, 4, 11. *https://doi.org/10.1186/1478-7954-4-11.*

[248] Theis KA, Murphy LB, Baker NA, & Hootman JM. (2019). When you can't walk a mile: Walking limitation prevalence and associations among middle-aged and older US adults with Arthritis: A cross-sectional, population-based study. *ACR Open Rheumatol*, 1(6), 350–358. *https://doi.org/10.1002/acr2.11046.*

[249] Centers for Disease Control and Prevention (CDC). Osteoarthritis (OA). Accessed March 8, 2019. Available at: *https://www.cdc.gov/arthritis/basics/osteoarthritis.htm.*

[250] Rissanen P, Aro S, Slatis P, et al. (1995). Health and quality of life before and after hip or knee arthroplasty. *The Journal of arthroplasty*, 10(2), 169–175. *https://doi.org/10.1016/s0883-5403(05)801238.*

[251] Ritter MA, Albohm MJ, Keating EM, et al. (1995). Comparative outcomes of total joint arthroplasty. *The Journal of arthroplasty*, 10(6), 737–741. *https://doi.org/10.1016/s0883-5403(05)80068-3.*

[252] Sayah SM, Karunaratne S, Beckenkamp PR, et al. (2021). Clinical Course of Pain and Function

Continued

patients experience benefit from these procedures.[253] Many patients note that their pre-operative expectations for functional improvement have not been met.[254 255 256 257] In addition, clinical practice variation has been well documented in the United States,[258 259 260 261 262] readmission and complication rates vary across hospitals,[263] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[264]

Due to the absence of recently conducted large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.[265] Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[266 267] are influenced by a range of improvements in care,[268] and demonstrate hospital-level variation even after patient case mix adjustment. [269 270] Further, THA/TKA procedures are specifically intended to improve function and reduce pain, making PROs a meaningful outcome metric to assess.[271]

In the CY 2021 OPPS/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL).[272] As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings.

We analyzed Part B Medicare FFS claims data for the number of HOPD claims with THA/TKA procedures during CY 2020, 2021, and 2022 (Table 65).

BILLING CODE 4120–01–P

Following Total Knee Arthroplasty: A Systematic Review and Meta-Regression. *J Arthroplasty*, 36(12), 3993–4002.e37. *https://doi.org/10.1016/j.arth.2021.06.019.*

[253] National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: *https://www.hqip.org.uk/resource/national-joint-registry-9th-annual-report-2012/.*

[254] Suda AJ, Seeger JB, Bitsch RG, et al. (2010). Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. *Orthopedics*, 33(2), 76–80. *https://doi.org/10.3928/01477447-20100104-07.*

[255] Ghomrawi HM, Franco Ferrando N, Mandl LA, et al. (2011). How Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. *HSS journal: The musculoskeletal journal of Hospital for Special Surgery*, 7(3), 229–234. *https://doi.org/10.1007/s11420-011-9203-6.*

[256] Harris IA, Harris AM, Naylor JM, et al. (2013). Discordance between patient and surgeon satisfaction after total joint arthroplasty. *The Journal of arthroplasty*, 28(5), 722–727. *https://doi.org/10.1016/j.arth.2012.07.044.*

[257] Jourdan C, Poiraudeau S, Descamps S, et al. (2012). Comparison of patient and surgeon expectations of total hip arthroplasty. *PloS one*, 7(1), e30195. *https://doi.org/10.1371/journal.pone.0030195.*

[258] Roos EM. (2003). Effectiveness and practice variation of rehabilitation after joint replacement. *Current opinion in rheumatology*, 15(2), 160–162. *https://doi.org/10.1097/00002281-200303000-00014.*

[259] Anderson FA, Huang W, Friedman RJ, et al. (2012). Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. *The Journal of arthroplasty*, 27(5), 659–666 e655. *https://doi.org/10.1016/j.arth.2011.09.001.*

[260] American Academy of Orthopaedic Surgeons. (2011). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. *https://www.aaos.org/globalassets/quality-and-practice-resources/vte/vte_full_guideline_10.31.16.pdf.*

[261] Pincus D, et al. (2020). Association Between Surgical Approach and Major Surgical Complications in Patients Undergoing Total Hip Arthroplasty. *JAMA*, 323(11), 1070–1076. *https://doi.org/10.1001/jama.2020.0785.*

[262] Siebens HC, Sharkey P, Aronow HU, et al. (2016). Variation in Rehabilitation Treatment Patterns for Hip Fracture Treated With Arthroplasty. *PM&R*, 8(3), 191–207. *https://doi.org/10.1016/j.pmrj.2015.07.005.*

[263] Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013. Available at: *http://qualitynet.org/.*

[264] Rolfson O. (2010). Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. Accessed July 20, 2013. Available at: *https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1.*

[265] Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: *https://innovation.cms.gov/innovation-models/cjr*

[266] Liebs TR, Herzberg W, Ruther W, et al. (2016). Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. *Archives of physical medicine and rehabilitation*, 97(5), 691–700. *https://doi.org/10.1016/j.apmr.2015.12.021.*

[267] White D, & Master H. (2016). Patient Reported Measures of Physical Function in Knee Osteoarthritis. *Rheum Dis Clin North Am*, 42(2), 239–252. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853650/.*

[268] Kim K, Anoushiravani A, Chen K, et al. (2019). Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. *Journal of Arthroplasty*, 34(7), S91–S96. *https://doi.org/10.1016/j.arth.2019.01.020.*

[269] Bozic KJ, Grosso LM, Lin Z, et al. (2014). Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. *The Journal of Bone and Joint Surgery*, 96(8), 640–647. *https://doi.org/10.2106/JBJS.L.01639.*

[270] Makela KT, Peltola M, Sund R, et al. (2011). Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. *Annals of medicine*, 43(sup1), S31–S38. *https://doi.org/10.3109/07853890.2011.586362.*

[271] Liebs T, Herzberg W, Gluth J, et al. (2013). Using the patient's perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. *The Bone & Joint Journal*, 95(B), 239–243. *https://doi.org/10.1302/0301-620X.95B2.28383.*

[272] Centers for Medicare & Medicaid Services. Ambulatory Surgical Center (ASC) Payment. Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment.*

TABLE 65: Distribution of Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) claims per Outpatient Hospital CY 2020-2021

CY Year	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2020	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2341	13	30.26	43.81	1	394
2020	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	2668	23	49.57	68.65	1	644
2020	27130 and 27447	All THA/TKA	2753	31	73.77	106.50	1	978

CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2021	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2619	18	37.80	53.19	1	540
2021	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	2901	30	60.75	86.08	1	1259
2021	27130 and 27447	All THA/TKA	2961	43	92.95	133.68	1	1400

CY	CPT	CPT Description	#HOPDs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2022	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	2756	21	42.09	63.69	1	1447
2022	27447	ARTHRP KNE CONDYLE&PLATU MEDIAL&LAT COMPARTMENTS	3001	36	70.24	98.70	1	1625
2022	27130 and 27447	All THA/TKA	3070	51	106.45	157.11	1	3072

Data source: Part B outpatient claims January 1, 2020 - December 31, 2022 with a CPT code of 27130 or 27447. Claims indicating an ED visit are excluded.

BILLING CODE 4120–01–C

In CY 2022 OPPS/ASC proposed rule (86 FR 42251 through 42252), we requested comment on the potential future adoption of the THA/TKA PRO–PM into the Hospital OQR Program. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63896 through 63898) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO–PM to the Hospital OQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the Hospital OQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. While we recognize that PRO based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision-making and benefits patients by engaging them in discussions about potential outcomes. Furthermore, we do not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully selected, with extensive input from interested parties, to be low burden for patients. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63851 through 63854) for a complete summary of feedback.

We propose to adopt the THA/TKA PRO–PM into the Hospital OQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025 through December 31, 2025, and the second would begin with the CY 2026 reporting period for eligible elective outpatient procedures between January 1, 2026 through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027 through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because this proposed measure requires collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there is a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the Hospital OQR Program, and when payment determinations occur. Therefore, we propose a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment determination) for the Hospital OQR Program. We refer readers to section XIV.E.7.a of this

proposed rule for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed in HOPDs and does not include any inpatient procedures. The measure excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounter) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).[273]

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee Injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, as proposed, accounts for potential non-response bias through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (FR 87 49246 through 49257), for more information on the development of the hospital-level THA/TKA PRO–PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

(i) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XIV.B.3.b(1) of this proposed rule, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with health care or treatment. These patient-reported data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of the proposed rule.[274] The measure includes PRO data collected with the PRO instruments described in this section of the proposed rule, among them are two joint-specific PRO instruments—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, HOPDs would submit one of two additional PRO instruments, all of the items in either the: (1) Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or (2) Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. Claims data billed under OPPS would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical co-morbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XIV.B.3.b(2)(a)(iii) of this proposed rule for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The HOPD facility-level THA/TKA PRO–PM result is calculated by aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary THA or TKA procedures performed at HOPDs for which complete and matched pre- and post-operative PRO data have been submitted, divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the requests for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and the CY 2022 OPPS/ASC proposed rule (FR 86 42251 through 42252) and the adoption of the measure in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we propose to adopt the THA/TKA PRO–PM in the Hospital OQR Program utilizing flexible data submission approaches.

[273] U.S. Department of Health and Human Services. (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, –73, and –74 for Reduced or Discontinued Services. Available at: *https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or.*

[274] Higgins JP, Thomas J, Chandler J, et al. (2019). Cochrane handbook for systematic reviews of interventions. John Wiley & Sons. *https://doi.org/10.1002/9781119536604.*

HOPDs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient reported outcome measure version; PROMIS Global (mental health subscale items) or VR–12 (mental health subscale items); HOOS, JR (for THA patients) or KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question [275] [276]).

HOPDs would submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date, date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients) or HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM would also serve as the review and correction period. Data would not be able to be corrected following the submission deadline.

We propose a phased implementation approach for adoption of this measure to the Hospital OQR Program, with voluntary reporting periods in CYs 2025 and 2026 followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

Voluntary reporting prior to mandatory reporting would allow time for facilities to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to comments from interested parties, as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and FY 2023 IPPS/LTCH PPS final rule (FR 87 49246 through 49257). Following the two voluntary reporting periods, we propose mandatory reporting of the THA/TKA PRO–PM beginning with the CY 2027 reporting period/CY 2030 payment determination. For each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM for the Hospital OQR in the publicly available ''2022 Measures Under Consideration List'' (MUC 2022–026).[277] The MAP Coordinating Committee supported the measure, as referenced in the 2022–2023 Final Recommendations report to HHS and CMS.[278]

The MAP members noted that a similar version of this measure has been adopted for use in the Hospital IQR Program, however, there currently is no measure that assesses PROs among THA/TKA patients in HOPDs for the Hospital OQR Program. The MAP highlighted that the key strategy for the Hospital OQR Program is to ensure that procedures done in any type of facility, including HOPDs, have equivalent quality. As such, the MAP members agreed that measures of quality of procedures in hospital settings should extend to HOPDs, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types.[279]

In addition, the MAP members stated that the goal of the PRO–PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family engagement and communication/care coordination for the Hospital OQR program.[280]

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO–PM (CBE #3559) in November 2020.[281] We note that the HOPD version of the THA/TKA PRO–PM would use the same specifications as the CBE-endorsed hospital-level THA/TKA PRO–PM that is currently implemented in the Hospital IQR program with modifications to capture procedures for the HOPDs. We intend to seek CBE endorsement for the HOPD version of the THA/TKA PRO–PM in a future endorsement cycle.

We have noted in previous rulemaking (75 FR 72064) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. We propose this measure without CBE endorsement based upon strong MAP and public support combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital level (CBE #3559). We expect that the measure will perform similarly in the HOPD setting, and we intend on submitting the measures for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XIV.E.7.a of this proposed rule for a discussion on the proposed THA/TKA PRO–PM form, manner, and timing submission requirements.

We invite public comment on this proposal.

c. Proposed Adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) Measure Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

The use of computed tomography (CT) scans has greatly improved the diagnosis and treatment of many conditions, and as such, over 80 million CT scans are performed each year in the US.[282] Most CT scans are performed as

[275] Fairbank JC, & Pynsent PB. (2000). The Oswestry Disability Index. Spine. 25(22), 2940–52. *https://doi.org/10.1097/00007632-200011150-00017.*

[276] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

[277] Centers for Medicare & Medicaid Services. 2022 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

[278] MAP MUC Preliminary Recommendations 2022–2023. Available at *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[279] Ibid.

[280] Ibid.

[281] Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: *https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618.*

[282] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

outpatient procedures.[283] CT scans expose patients to low-dose ionizing radiation which is known to contribute to the development of cancer.[284] The Biological Effects of Ionizing Radiation (BEIR) VII report by the United States National Academy of Sciences defined low-dose radiation as doses up to 100 millisieverts (mSv).[285] A low dose CT scan of the chest delivers 1.5 mSv of radiation, while a regular-dose CT chest scan delivers 7 mSv of radiation.[286] In comparison, a conventional chest x-ray delivers about 0.1 mSv of radiation.[287]

There is a large body of research that suggests that exposure to ionizing radiation within the same range that is routinely delivered by CT scans increases a person's risk of developing cancer.[288] [289] [290] [291] One study found that patients who received CT scans, particularly women and adults aged 45 years or younger, had an elevated risk of developing thyroid cancer and leukemia.[292] Another study found that patients who received CT scans had a 0.7 percent higher risk of developing cancer in their lifetime compared to the general United States population.[293] Cancer risk increased for patients who underwent multiple CT scans, ranging from 2.7 to 12 percent.[294] While the likelihood of developing cancer from a CT scan is small on an individual level, it has been estimated that the percentage of cancers attributable to CT scans in the United States may be as high as two percent.[295]

CT image quality and radiation dose are related; as radiation dose increases, image quality increases until a diagnostic threshold is reached, at which point no further diagnostic benefit from image quality occurs.[296] [297] Conversely, too little radiation dose can produce inadequate image quality. Research suggests that current radiation doses utilized for CT scans may be lowered between 50 percent and 90 percent without impacting image diagnostic utility. [298] [299] [300] [301] [302] Based on the evidence of harm from excessive radiation and evidence that radiation doses could be lowered in many patients' situation without deteriorating image diagnostic utility to the point of rendering exams unacceptable, we believe it is important to promote patient safety by ensuring that patients are exposed to the lowest possible level of radiation while preserving image quality.

(2) Overview of Measure

The Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM) (the Excessive Radiation eCQM), which was developed by the University of California San Francisco and is stewarded by Alara Imaging, Inc., provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure calculates the percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.[303] This measure provides a metric toward reducing unintentional harm to patients from CT scans. Setting a standard for diagnostic CT scans to prevent unnecessarily high radiation doses while preserving image quality would provide hospitals with a reliable method to assess harm reduction efforts and modify their improvement efforts. This measure also addresses high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.[304] Additionally, the Excessive Radiation eCQM supports the National Quality Strategy goal of promoting safety because it works to reduce preventable harm to patients.[305] The measure was developed according to evidence and consensus-based clinical guidelines for optimizing CT radiation doses, including guidelines developed by the American College of Radiology, American College of Cardiology, Image Wisely 2020, and the

[283] Food and Drug Administration. Computed Tomography. Available at: *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct.*

[284] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[285] Siegel JA, Greenspan BS, Maurer AH, et al. (2018). The BEIR VII Estimates of Low-Dose Radiation Health Risks Are Based on Faulty Assumptions and Data Analyses: A Call for Reassessment. Journal of Nuclear Medicine, 59 (7) 1017–1019. *https://doi.org/10.2967/jnumed.117.206219.*

[286] Ibid.

[287] Environmental Protection Agency. Radiation Sources and Doses. Available at: *https://www.epa.gov/radiation/radiation-sources-and-doses.*

[288] Berrington de Gonzalez A, Daniels RD, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Rationale and Framework for the Monograph and Overview of Eligible Studies. J Natl Cancer Inst Monogr, 2020(56), 97–113. *https://doi.org/10.1093/jncimonographs/lgaa009.*

[289] Cao CF, Ma KL, Shan H, et al. (2022). CT Scans and Cancer Risks: A Systematic Review and Dose-response Meta-analysis. BMC Cancer, 22, 1238. *https://doi.org/10.1186/s12885-022-10310-2.*

[290] Hauptmann M, Daniels R, Cardis E, et al. (2020). Epidemiological Studies of Low-Dose Ionizing Radiation and Cancer: Summary Bias Assessment and Meta-Analysis. J Natl Cancer Inst Monogr, 2020(56), 188–200. *https://doi.org/10.1093/jncimonographs/lgaa010.*

[291] Shao YH, Tsai K, Kim S, Wu YJ, Demissie K. (2020). Exposure to Tomographic Scans and Cancer Risks. JNCI Cancer Spectr, 4(1). *https://doi.org/10.1093/jncics/pkz072.*

[292] Ibid.

[293] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[294] Ibid.

[295] Berrington de González A, Mahesh M, Kim KP, et al. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. Archives of internal medicine, 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

[296] Goldman LW. (2007). Principles of CT: Radiation Dose and Image Quality. Journal of Nuclear Medicine Technology, 35(4), 213–225. *https://doi.org/10.2967/jnmt.106.037846.*

[297] Smith-Bindman R, Chu P, Wang Y, Chung R, et al. (2020). Comparison of the Effectiveness of Single-Component and Multicomponent Interventions for Reducing Radiation Doses in Patients Undergoing Computed Tomography: A Randomized Clinical Trial. JAMA Intern Med, 180(5), 666–675. *https://doi.org/10.1001/jamainternmed.2020.0064.*

[298] Greffier J, Hamard A, Pereira F, et al. (2020). Image quality and dose reduction opportunity of deep learning image reconstruction algorithm for CT: a phantom study. Eur Radiol, 30(7), 3951–3959. *https://doi.org/10.1007/s00330-020-06724-w.*

[299] Gottumukkala RV, Kalra MK, Tabari A, Otrakji A, Gee MS. (2019). Advanced CT Techniques for Decreasing Radiation Dose, Reducing Sedation Requirements, and Optimizing Image Quality in Children. Radiographics, 39(3), 709–726. *https://doi.org/10.1148/rg.2019180082.*

[300] Den Harder AM, Willemink MJ, van Doormaal PJ, et al. (2018). Radiation dose reduction for CT assessment of urolithiasis using iterative reconstruction: A prospective intra-individual study. Eur Radiol, 28(1), 143–150. *https://doi.org/10.1007/s00330-017-4929-2.*

[301] Rob S, Bryant T, Wilson I, Somani BK. (2017). Ultra-low-dose, low-dose, and standard-dose CT of the kidney, ureters, and bladder: is there a difference? Results from a systematic review of the literature. Clin Radiol, 72(1), 11–15. *https://doi.org/10.1016/j.crad.2016.10.005.*

[302] Konda SR, Goch AM, Leucht P, et al. (2016). The use of ultra-low-dose CT scans for the evaluation of limb fractures: is the reduced effective dose using CT in orthopaedic injury (REDUCTION) protocol effective? Bone Joint J, 98–B(12), 1668–1673. *https://doi.org/10.1302/0301-620X.98B12.BJJ-2016-0336.R1.*

[303] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[304] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[305] Centers for Medicare & Medicaid Services. CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

American Association of Physicists in Medicine. [306] [307] [308] [309]

Measure testing by the measure developer across a total of 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices revealed that availability, accuracy, validity, and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The measure developer further assessed the reporting burden by administering surveys to each of the participating hospitals and outpatient groups. The measure developer found the burden to be small to moderate, comparable to the burden of measure reporting for other measures. Additionally, the measure developer noted that the burden of reporting the Excessive Radiation eCQM fell to information technology personnel rather than physicians.

Measure testing found that assessing radiation doses and providing audit feedback to radiologists resulted in significant reductions in dose levels. The testing sites also noted that the assessment of their doses as specified in the measure was helpful for identifying areas for quality improvement. According to the measure developer, over 40 letters were submitted in support of the measure, including several from radiologists and medical physicists who serve as leaders of the testing sites, that confirmed the measure was feasible and that data assembly would not pose a large burden.

The Excessive Radiation eCQM was submitted to the CBE for endorsement review in the Fall 2021 cycle (CBE #3663e) and was endorsed on August 2, 2022. The measure was also included in the 2022 MUC List.[311] The MAP Hospital Workgroup reviewed the MUC List on December 13–14, 2022. The Workgroup noted that the Hospital OQR Program currently does not have any measures assessing the risk of radiation exposure from CT scans. The Workgroup also noted that the measure addresses the ''Safety'' Meaningful Measures 2.0 Healthcare Priority and would encourage shared decision-making between providers and patients.[312] The MAP's Final Report on February 1, 2023 supported the Excessive Radiation eCQM for rulemaking in the Hospital OQR Program.[313]

(3) Data Sources

The Excessive Radiation eCQM uses hospitals' electronic health record (EHR) data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted Digital Imaging and Communications in Medicine (DICOM) standard. Currently, eCQMs cannot access and process data elements in their original DICOM formats.

Hospitals may choose to use any available software that performs the necessary functions to comply with measure requirements. One such example is the Alara Imaging software,[314] which fulfills these requirements by linking primary data elements, assessing CT scans for eligibility for inclusion in the measure, and generating three data elements mapped to clinical terminology for EHR consumption (CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise) within the hospital's firewall.[315] While the Alara Imaging software and the necessary updates to the software are proprietary, these would be available to all reporting entities free of charge and accessible by creating a secure account through the measure steward's website. Alara Imaging Inc. would also provide free of charge necessary education materials including step-by-step instructions on creating an account and linking their EHR and PACS data to the software. Hospitals and their vendors would be able to use the data elements created by this software to calculate the eCQM and to submit results to the Hospital OQR Program via Quality Reporting Document Architecture (QRDA) Category I files as they do for all other eCQMs.

(4) Measure Specifications

The measure numerator is diagnostic CT scans that have a size-adjusted radiation dose greater than the threshold defined for the specific CT category. The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam. The numerator also includes CT scans with a noise value greater than a threshold specific to the CT category.[316]

The measure denominator is all diagnostic CT scans performed on patients ages 18 and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.[317]

The measure excludes CT scans that cannot be categorized by the area of the body being imaged or reason for imaging. These include scans that are simultaneous exams of multiple body regions outside of four commonly performed multiple region exams defined by the measure, or scans that cannot be classified based on diagnosis and procedure codes. Exams that cannot be classified are specified as LOINC code 96914–7, CT Dose and Image Quality Category, Full Body. The measure also has technical exclusions for CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise. We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/ecqm/oqr/pre-rulemaking/2024/cms1206v1#quicktabs-tab-tabs_pre_rule_measure-0*) for more details on the measure specifications.

(5) Data Submission and Reporting

We propose the adoption of the Excessive Radiation eCQM as a voluntary measure for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure. We refer readers to section XIV.E.6.b of this proposed rule for a discussion of the Excessive Radiation eCQM reporting and data

[306] American College of Radiology. (2015). Development and Revision Handbook. Available at: *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf.*

[307] Hirshfeld JW, Ferrari VA, Bengel FM, et al. (2018). 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: *Best Practices for Safety and Effectiveness. Catheter Cardiovasc Interv*, 2018(92), E35–E97. *https://doi.org/10.1002/ccd.27659.*

[308] Image Wisely 2020. Available at: *https://www.imagewisely.org/Imaging-Modalities/Computed-Tomography/Diagnostic-Reference-Levels.*

[309] American Association of Physicists in Medicine. The Alliance For Quality Computed Tomography. Available at: *https://www.aapm.org/pubs/CTProtocols/.*

[311] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[312] Ibid.

[313] Ibid.

[314] Alara Imaging. Available at: *https://www.alaracare.com/.*

[315] Additional information on measure software security and processes is available at *https://www.alaracare.com/our-solutions.*

[316] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[317] Ibid.

submission requirements. We also refer readers to section XIV.E.6 of this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies.

We invite public comment on this proposal.

4. Previously Finalized and Proposed Hospital OQR Program Measure Sets

a. Summary of Previously Finalized and Newly Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination

We refer readers to the CY 2023 OPPS/ASC final rule (87 FR 72100 through 72102) for a summary of the previously finalized Hospital OQR Program measure set for the CY 2025 payment determination. Table 66 summarizes the previously finalized and newly proposed Hospital OQR Program measures for the CY 2026 payment determination:

BILLING CODE 4120–01–P

TABLE 66: Proposed Hospital OQR Program Measure Set for the CY 2026 Payment Determination

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
0658	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)*
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) – About Facilities and Staff***
None	OAS CAHPS – Communication About Procedure***
None	OAS CAHPS – Preparation for Discharge and Recovery***
None	OAS CAHPS – Overall Rating of Facility***
None	OAS CAHPS – Recommendation of Facility***
3636	COVID-19 Vaccination Coverage Among Health Care Personnel*
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infraction (STEMI) electronic clinical quality measure (eCQM)****

†We note that CBE endorsement for this measure was removed.

* In this proposed rule, we propose a measure modification to Colonoscopy Follow-Up Interval beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In the CY 2023 OPPS/ASC final rule (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for the Cataracts Visual Function measure for the CY 2025 reporting period and subsequent years. In this proposed rule, we propose to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period.

*** In the CY 2022 OPPS/ASC final rule (86 FR 63840), we finalized voluntary reporting beginning with the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

**** In this proposed rule, we propose a measure modification to COVID-19 Vaccination Coverage Among HCP beginning with the CY 2024 reporting period/CY 2026 payment determination.

***** The STEMI eCQM was adopted in the CY 2022 OPPS/ASC final rule (86 FR 63837 through 63840), beginning with voluntary reporting for the CY 2023 reporting period and mandatory reporting beginning with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Previously Finalized and Newly Proposed Hospital OQR Program Measure Set for the CY 2027 Payment Determination and Subsequent Years

Table 67 summarizes the previously finalized and newly proposed Hospital OQR Program measures beginning with the CY 2027 payment determination and subsequent years:

TABLE 67: Proposed Hospital OQR Program Measure Set for the CY 2027 Payment Determination and Subsequent Years

CBE #	Measure Name
0514	MRI Lumbar Spine for Low Back Pain†
None	Abdomen CT – Use of Contrast Material
0669	Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low-Risk Surgery
0496	Median Time for Discharged ED Patients (Previously referred to as Median Time from ED Arrival to ED Departure for Discharged ED Patients)
0661	Head CT or MRI Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival
None	HOPD Procedure Volume (Previously referred to as Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures)*
0658	Colonoscopy Follow-Up Interval (Previously referred to as Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients)
1536	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)**
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
3490	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
2687	Hospital Visits after Hospital Outpatient Surgery
None	OAS CAHPS – About Facilities and Staff
None	OAS CAHPS – Communication About Procedure
None	OAS CAHPS – Preparation for Discharge and Recovery
None	OAS CAHPS – Overall Rating of Facility
None	OAS CAHPS – Recommendation of Facility
3636	COVID–19 Vaccination Coverage Among Health Care Personnel
None	Breast Cancer Screening Recall Rates
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM
None	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM)
3663e	Excessive Radiation eCQM (Previously referred to as Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM)****

†We note that CBE endorsement for this measure was removed.

* In this proposed rule, we propose to re-adopt the HOPD Procedure Volume measure with modification beginning with the voluntary CY 2025 reporting period and mandatory beginning with the CY 2026 reporting period/CY 2028 payment determination.

** In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72097 through 72099), we finalized keeping data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.

***In this proposed rule, we propose to adopt the THA/TKA PRO–PM beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory beginning with the CY 2027 reporting period/CY 2030 payment determination.

****In this proposed rule, we propose to adopt the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period and mandatory beginning with the CY 2026 reporting period/CY 2028 payment determination.

BILLING CODE 4120–01–C

5. Maintenance of Technical Specifications for Quality Measures

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59104 and 59105) and the CY 2022 OPPS/ASC final rule (86 FR 63861) for our policies regarding maintenance of technical specifications for quality measures. We maintain technical specification manuals that can be found on the CMS website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. Technical specifications for eCQMs used in the Hospital OQR Program are contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update), which are available, along with implementation guidance documents, on the eCQI Resource Center website at: *https://ecqi.healthit.gov/*.

We are not proposing any changes to these policies in this proposed rule.

6. Public Display of Quality Measures

We refer readers to the CY 2009, CY 2014, CY 2017, and CY 2021 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, 81 FR 79791, and 85 FR 86193 through 86236 respectively) for our previously finalized policies regarding public display of quality measures.

We are not proposing any changes to these policies in this proposed rule.

a. Public Reporting Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate

The Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086). The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time. The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: Median Time for Discharged ED Patients—Reported Measure, which excludes psychiatric/mental health and transferred patients; Median Time for Discharged ED Patients-Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; and Median Time for Discharged ED Patients—Transfer Patients, which includes information only for patients transferred from the ED; along with the Median Time for Discharged ED Patients-Overall Rate. The measure excludes patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.

In the CY 2011 OPPS/ASC final rule (75 FR 72086), we considered publicly displaying all strata; however, due to input from interested parties, we did not finalize public display of Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate. Currently, measure data for the Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate are not reported publicly on the Care Compare site. Measure data for the Median Time for Discharged ED Patients—Reported Measure is currently publicly displayed on the Care Compare site and in the corresponding downloadable data file for the Hospital OQR Program. We also collect and report Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients for public awareness of behavioral health gaps in the transfer of such patients, and per the CY 2018 OPPS/ASC final rule (82 FR 59437), we adopted a policy to publicly report these stratified behavioral health data beginning in July 2018 using data from patient encounters during the third quarter of 2017. We now believe displaying all strata will highlight and prioritize various issues in the health care system, specifically behavioral health and continuum of care.

We propose publicly reporting measure data for Median Time for Discharged ED Patients—Transfer Patients and Median Time for Discharged ED Patients—Overall Rate. Publicly reporting these measure stratifications can elucidate ED throughput performance gaps for patients requiring higher levels of specialized care above what a facility is able to or provide. Data for these measure stratifications are not currently being reported publicly on the Care Compare site.

Beginning with the CY 2024, we propose to make data publicly available on our Care Compare website and in downloadable data files found at *data.cms.gov* for the following chart-abstracted measure strata: Median Time for Discharged ED Patients—Transfer Patients and the Median Time for Discharged ED Patients—Overall Rate which contains data for all patients.

We invite public comment on this proposal.

b. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website. We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86193 through 86236) for our previously finalized policies regarding the Overall Star Ratings.

We are not proposing any changes to these policies in this proposed rule.

C. Hospital OQR Program Quality Measure Topics for Potential Future Consideration

1. Summary

We seek public comment on potential measurement topic areas for the Hospital OQR Program. This request for comment (RFC) seeks input on innovative measurement approaches and data sources for use in quality measurement to inform our work and, more specifically, the focus of measure development within the Hospital OQR Program. We identified three potential priority areas and we encourage the public to review and provide comment.

2. Background

We are seeking public comment to address: (1) quality measurement gaps in the HOPD setting, including the ED; (2) changes in outpatient care (such as shifts in volume, technology use, and case complexity); (3) growth of concerns around workforce and patient safety; (4) the transition to digital quality measurement; and (5) interest in patient-reported outcomes.

Specifically, we seek comment on quality measurement topics for the Hospital OQR Program that include:

- Promoting Safety (Patient and Workforce);
- Behavioral Health; and
- Telehealth.

We seek input on the specific questions posed in this RFC.

3. Solicitation of Comments on Patient and Workforce Safety as a Measurement Topic Area in the Hospital OQR Program

Launched in April 2022, the CMS National Quality Strategy outlines CMS' aim to shape a resilient, high-value healthcare system through quality outcomes, safety, equity, and accessibility for all.[318] Improving safety

[318] Schreiber M, Richards AC, Moody-Williams J, et al. (2022). The CMS National Quality Strategy: A

through levers such as quality measurement is a critical objective of the National Quality Strategy. We acknowledge that promoting safety in order to achieve zero preventable harm requires developing measures that assess and hold healthcare systems accountable to keep individuals safe through preventative and treatment processes. Therefore, in this proposed rule, we are seeking public comment on patient and workforce safety measures. We are particularly interested in sepsis care for potential future inclusion in the Hospital OQR Program as a patient safety measure.

Sepsis is a life-threatening condition which can arise from simple infections (such as pneumonia or a urinary tract infection) and requires prompt recognition and early intervention, which can often occur in an ED.[319] [320] Although sepsis can affect anyone at any age, it is more common in infants, older adults, and patients with chronic health conditions such as diabetes and immunosuppressive disorders.[321] The Centers for Disease Control and Prevention (CDC) estimates annually that there are approximately 1.7 million adults diagnosed with sepsis with 270,000 resulting deaths.[322] Therefore, preventing, diagnosing, and treating sepsis effectively has been a focus of patient safety in recent years.[323] [324]

HOPDs may play a critical role in the initial assessment and evaluation of suspected sepsis patients through lab tests, diagnostic imaging, and collection of sepsis biomarkers.[325] Timely and accurate sepsis diagnosis is essential to effective care. Research shows that performance of evidence-based time-sensitive therapies in EDs can lower the risk of organ dysfunction, reduce mortality, and mitigate the need for mechanical ventilation.[326] [327] [328] In addition, using an interdisciplinary sepsis-response team to coordinate care in the ED shows potential in improving sepsis care management and enhancing patient outcomes.[329] These findings highlight the role of HOPDs and EDs in the timely diagnosis and treatment of sepsis. Therefore, we believe the Hospital OQR Program may benefit from quality measures centered around sepsis care.

We also believe quality measures should align, to the extent possible, across CMS programs to minimize reporting burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236 through 50241), we adopted the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500 [330]) (the Sepsis measure) into the Hospital Inpatient Quality Reporting (IQR) Program beginning with the FY 2015 reporting period/FY 2017 payment determination. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27027 through 27030), we proposed to adopt the Sepsis measure into the Hospital Value-Based Purchasing (HVBP) Program beginning with the FY 2026 program year. The Sepsis measure supports the efficient, effective, and timely delivery of high-quality sepsis care by providing a standard operating procedure for the early risk stratification and management of a patient with severe infection. When the care interventions in the measure are provided as a composite, health systems observe significant reductions in hospital length of stay, re-admission rates, and mortality.[331] [332]

We request comment on whether this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as whether CMS should consider adopting an alternative measure that assesses the quality of sepsis care in the hospital outpatient setting.[333]

Additional safety measures may be needed to adequately monitor and maintain safety in the Hospital OQR Program, such as measurement of system-wide all-cause harm, in addition to the safety of observation care, procedures and services, medication errors, technology, and workforce. Patient and workforce safety are interconnected, as the safety of healthcare workers is critical to maintaining a safe and effective healthcare environment.[334]

We are requesting input from interested parties on the following topics: (1) safety outcome priorities specific to settings, services, transitions and transfers, and access to care; (2) general cross-outpatient setting outcomes; (3) individual harms, including methodological approaches to patient identification and data collection, technological-derived harm, and use of electronic resources to mitigate potential for harm; and (4) workforce safety. Specifically, we are requesting comment on the following questions:

- What are interested parties' highest priority outcomes for ensuring safety in the outpatient setting, not limited to the following: overall priorities; priorities for specific settings (for example, EDs, HOPDs) and services (for example, observation care, emergent and non-emergent surgeries, procedures, and imaging); safety related to transitions between care settings; and safety around access to care (for example, a patient who lacks access to life-saving

Person-Centered Approach to Improving Quality. Available at: *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[319] McVeigh SE. (2020). Sepsis Management in the Emergency Department. *The Nursing clinics of North America*, 55(1), 71–79. *https://doi.org/10.1016/j.cnur.2019.10.009.*

[320] Seymour CW, Gesten F, Prescott HC, et al. (2017). Time to Treatment and Mortality during Mandated Emergency Care for Sepsis. *The New England journal of medicine*, 376(23), 2235–2244. *https://doi.org/10.1056/NEJMoa1703058.*

[321] National Institute of General Medical Sciences. (2021). Sepsis. Available at: *https://nigms.nih.gov/education/fact-sheets/Pages/sepsis.aspx.*

[322] Centers for Disease Control and Prevention. (2022). What is Sepsis? Available at: *https://www.cdc.gov/sepsis/what-is-sepsis.html.*

[323] Rhee C, Dantes RB, Epstein L, & Klompas M. (2019). Using Objective Clinical Data to Track Progress on Preventing and Treating Sepsis: CDC's New 'Adult Sepsis Event' Surveillance Strategy. *BMJ Qual Saf*, 28(4), 305–309. *https://doi.org/10.1136/bmjqs-2018-008331.*

[324] Fay K, Sapiano MRP, Gokhale R, et al. (2020). Assessment of Health Care Exposures and Outcomes in Adult Patients with Sepsis and Septic Shock. *JAMA Netw Open*, 3(7), e206004. *https://doi.org/10.1001/jamanetworkopen.2020.6004.*

[325] Gauer R, Forbes D, & Boyer N. (2020). Sepsis: Diagnosis And Management. *American Family Physician*, 101(7), 409–418. *https://www.aafp.org/pubs/afp/issues/2020/0401/p409.html.*

[326] Arabi YM, Al-Dorzi HM, Alamry A, et al. (2017). The Impact of a Multifaceted Intervention Including Sepsis Electronic Alert System and Sepsis Response Team on the Outcomes of Patients with Sepsis and Septic Shock. *Annals of intensive care*, 7(1), 57. *https://doi.org/10.1186/s13613-017-0280-7.*

[327] Whiles BB, Deis AS, & Simpson SQ. (2017). Increased Time to Initial Antimicrobial Administration is Associated With Progression to Septic Shock in Severe Sepsis Patients. *Critical care medicine*, 45(4), 623–629. *https://doi.org/10.1097/CCM.0000000000002262.*

[328] Gavelli F, Castello LM, & Avanzi GC. (2021). Management of Sepsis and Septic Shock in the Emergency Department. *Internal and emergency medicine*. 16(6), 1649–1661. *https://doi.org/10.1007/s11739-021-02735-7.*

[329] Delawder JM, & Hulton L. (2020). An Interdisciplinary Code Sepsis Team to Improve Sepsis-Bundle Compliance: A Quality Improvement Project. *Journal of emergency nursing*, 46(1), 91–98. *https://doi.org/10.1016/j.jen.2019.07.001.*

[330] 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.

[331] Levy MM, Gesten FC, Phillips GS, et al. (2018). Mortality Changes Associated with Mandated Public Reporting for Sepsis: The Results of the New York State Initiative. *Am J Respir Crit Care Med*, 198(11), 1406–1412. *https://doi.org/10.1164/rccm.201712-2545OC.*

[332] Bauer SR, Han X, Wang XF, et al. (2020). Association Between Compliance with the Sepsis Quality Measure (SEP–1) and Hospital Readmission. *Chest*, 158(2), 608–611. *https://doi.org/10.1016/j.chest.2020.02.042.*

[333] Centers for Medicare & Medicaid Services. (2023). Sepsis Bundle Project (SEP) National Hospital Inpatient Quality Measures. Available at: *https://qualitynet.cms.gov/files/6391e95676962e0016ad9199?filename=2a-b_SEP-List_v5.14.pdf.*

[334] McGaffigan P, Gerwig K, & Kingston MB. (2020). Workforce Safety Key to Patient Safety. *Healthcare Executive*. 35(6), 48–50. *https://www.ihi.org/resources/Pages/Publications/workforce-safety-key-to-patient-safety.aspx.*

medications such as insulin, epinephrine, albuterol)?

• What outcomes should be measured across all settings within the Hospital OQR Program?

• Individual harms (such as wrong-site surgery) occur at low frequencies, presenting a challenge for the development of risk-adjusted quality measures that can be used to compare facilities. Existing measures in the Hospital OQR Program have used approaches such as the capture of utilization (for example, the Hospital Visits After Hospital Outpatient Surgery Measure (CBE #2687)) to indicate potential harm and longer measurement periods to improve measurement reliability.

++ Are there other methodological approaches or data that we could use to identify harm to patients receiving care in the outpatient setting?

++ What approaches could we use to capture harms associated with outpatient services (HOPD procedures, ED visits, outpatient clinic visits, outpatient imaging)?

++ How could electronic data sources or monitoring systems be leveraged to gather timely data on such errors?

• What aspects of workforce safety are important for us to consider for the Hospital OQR Program?

• As new technology becomes available and is used more widely (such as artificial intelligence (AI) for diagnoses, robotic surgery, and electronic health records (EHRs)), there is a potential for these technologies or their application to cause harm to patients. For example, AI algorithms trained on data that is under representative of certain racial, ethnic, or gender groups may misdiagnosis these same populations.[335] At the same time, technology could also be leveraged to mitigate AI risks, improve safety, or facilitate quality measurement.

++ Which technologies are of the most concern in terms of potential for harm?

++ What measurable safety-related outcomes should CMS consider for the Hospital OQR Program?

++ What technologies could be leveraged to improve safety or facilitate its measurement?

4. Solicitation of Comments on Behavioral Health and Suicide Prevention in the Hospital OQR Program

Behavioral healthcare in the outpatient setting comprises a vast array of services for patients with a wide range of conditions. Behavioral health services are delivered in multiple settings by multiple types of providers, including but not limited to HOPDs, through partial observation, and in the ED.

Quality gaps in the area of hospital outpatient behavioral health include care coordination across settings, availability of services, and barriers to accessing services. In this RFC, we are seeking comment from interested parties on behavioral health topics based in part on work by the National Quality Forum (NQF), The National Committee for Quality Assurance (NCQA), and the CMS Behavioral Health Strategy.[336] [337] [338] Behavioral health topics under consideration for measure development in the hospital outpatient setting include: availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm (that is, harm resulting from medical care), equity across all domains, and suicide prevention. We are particularly interested in measuring suicide screening in the hospital outpatient setting to improve early risk detection and facilitate appropriate behavioral health treatment.

Suicide is a serious but preventable public health threat and is one of the leading causes of death in the United States (US).[339] In 2020, about 46,000 Americans died as a result of suicide and 12.2 million adults experienced suicidal ideation.[340] Individuals with a recorded depressive disorder are about five times more likely to die by suicide after adjusting for sociodemographic factors and other mental health diagnoses than individuals without a recorded mental health condition.[341] Many factors contribute to suicide risk, including Major Depressive Disorder (MDD) diagnosis.[342] [343] MDD is a significant risk factor for suicide, indicating that patients with MDD are a critical population for intervention efforts.[344]

Research shows that in the weeks, months, and year prior to suicide, individuals significantly utilized healthcare services, providing an opportunity for assessment and prevention in the clinical setting.[345] Nineteen percent of individuals who died by suicide with a recorded mental health diagnosis visited the ED within one year prior to their death while 7.5 percent visited the ED within one month.[346] HOPDs may be an opportune setting for detecting suicide risk in persons with mental health diagnoses, such as MDD, and reducing the overall suicide rate. ED-initiated suicide prevention efforts can meaningfully reduce suicide attempts in individuals that are screened and receive evidence-based care.[347]

Under the Merit-based Incentive Payment System (MIPS), we adopted the Adult Major Depressive Disorder (MDD): Suicide Risk Assessment measure (CBE #0104). This measure

[335] Thomas, LB, Mastorides, SM, Viswanadhan, NA, et al. (2021). Artificial Intelligence: Review of Current and Future Applications in Medicine. *Federal practitioner: for the health care professionals of the VA, DoD, and PHS*, 38(11), 527–538. *https://doi.org/10.12788/fp.0174.*

[336] National Quality Forum. (2022). Opioid-Related Outcomes Among Individuals with Co-occurring Behavioral Health Conditions. Available at: *https://www.qualityforum.org/Projects/n-r/Opioids_and_Behavioral_Health_Committee/2022_Final_Report.aspx#onclick=%E2%80%9D_gaq.push([%E2%80%98_trackEvent%E2%80%99,%E2%80%99Download%E2%80%99,%E2%80%99PDF%E2%80%99,this.href]);%E2%80%9D* Using Measurement to Promote Joint Accountability and Whole-Person Care.

[337] The National Committee for Quality Assurance. (2021). Behavioral Health Quality Framework: A Roadmap for Using Measurement to Promote Joint Accountability and Whole-Person Care. Available at: *https://www.ncqa.org/wp-content/uploads/2021/07/20210701_Behavioral_Health_Quality_Framework_NCQA_White_Paper.pdf.*

[338] Centers for Medicare and Medicaid Services. (2022). CMS Behavioral Health Strategy. Available at: *https://www.cms.gov/cms-behavioral-health-strategy.*

[339] Centers for Disease Control and Prevention. (2022). Facts About Suicide. Available at: *http://www.cdc.gov/suicide/facts/index.html.*

[340] Centers for Disease Control and Prevention. (2022). Suicide Prevention. Available at: *http://www.cdc.gov/suicide/index.html.*

[341] Yeh HH, Westphal J, Hu Y, et al. (2019). Diagnosed Mental Health Conditions and Risk of Suicide Mortality. *Psychiatric services (Washington, DC)*, 70(9), 750–757. *https://doi.org/10.1176/appi.ps.201800346.*

[342] Ibid.

[343] Cai H, Xie XM, Zhang Q, et al. (2021). Prevalence of Suicidality in Major Depressive Disorder: A Systematic Review and Meta-Analysis of Comparative Studies. Frontiers in psychiatry, 12, 690130. *https://doi.org/10.3389/fpsyt.2021.690130.*

[344] Moitra M, Santomauro D, Degenhardt L, et al. (2021). Estimating the Risk of Suicide Associated with Mental Disorders: A Systematic Review and Meta-regression Analysis. *Journal of psychiatric research*, 137, 242–249. *https://doi.org/10.1016/j.jpsychires.2021.02.053.*

[345] Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. *JAMA psychiatry*, 74(6), 563–570. *https://doi.org/10.1001/jamapsychiatry.2017.0678.*

[346] Ahmedani BK, Simon GE, Stewart C, et al. (2014). Health Care Contacts in the Year Before Suicide Death. *J Gen Intern Med*, 29, 870–877. *https://doi.org/10.1007/s11606-014-2767-3.*

[347] Miller IW, Camargo CA, Arias SA, et al. (2017). Suicide Prevention in an Emergency Department Population: The ED–SAFE Study. *JAMA psychiatry*, 74(6), 563–570. *https://doi.org/10.1001/jamapsychiatry.2017.0678.*

aims to improve clinical assessment of suicide risk where a new or recurrent episode of MDD is identified and may be beneficial in the Hospital OQR Program. We request comment on this specific measure example, including whether interested parties believe this measure would be appropriate and feasible for use in the Hospital OQR Program, as well as other measures, such as a universal screening measure. More than half of those who die by suicide do not have a recorded mental health diagnosis.[348] Universal suicide screening may improve identification of individuals who may not otherwise have been identified as at risk.[349]

Additional measures may be needed to adequately promote screening and treatment of behavioral health disorders in the outpatient setting. For example, measures geared towards prevention and treatment of substance use disorders. In 2021, 17.3 percent of adults over the age of 18 met the criteria for substance use disorder for drugs or alcohol.[350] Outpatient screening of substance use disorders through tools such as SAMHSA's Screening, Brief Intervention, and Referral to Treatment (SBIRT) may aid the early intervention and treatment for persons with substance use disorders and help identify those at risk of developing such disorders.[351] [352] We seek comment on whether screening for substance use disorders would be an appropriate measure topic for the Hospital OQR Program.

Furthermore, we seek broad input on behavioral health as a measurement topic area in the Hospital OQR Program based on, but not limited to, the following matters: (1) priorities for measuring outcomes of outpatient behavioral health services, particularly by setting within the HOPD; and (2) quality measure approaches to improve behavioral health access in outpatient settings. Specifically, we are requesting comment from interested parties on the following questions:

- Are there additional behavioral health topic areas that we should prioritize? Of the topics outlined in this RFC (availability and access, coordination of care, patient experience, patient-centered clinical care, prevention and treatment of chronic conditions, prevention of iatrogenic harm, equity across all domains, and suicide prevention), which are the highest priority? What are the most relevant quality gaps and outcomes related to behavioral health for hospital outpatient settings and services?
- Access is one of the biggest challenges around improving behavioral health outcomes. What measurement approaches could be used to drive improvements in access to services?
- Should CMS consider substance use disorder-related screening and counseling measures in regards to behavioral health outcomes for the outpatient setting, and, if so, what specific quality measures should CMS include?
- Should CMS consider a measure related to universal suicide risk in the ED? Are there other interventions or measurement approaches targeted at suicide prevention that CMS should consider?

5. Solicitation of Comments on Telehealth as a Measurement Topic Area in the Hospital OQR Program

We define telehealth as the provision of healthcare services through two-way, real-time interactive telecommunications technology between patients and providers who are located at a distant site.[353] Telemedicine has the potential to improve patient experience, outcomes, and access to healthcare.[354] Telemedicine is also associated with cost-savings for both patients and healthcare systems.[355] [356] Telehealth utilization expanded greatly in the outpatient setting during the early months of the SARS–CoV–2 pandemic.[357] The number of outpatient visits conducted via telehealth has since declined but remains higher than pre-pandemic levels.[358]

While telehealth provides a variety of benefits to patients and health systems, there is variability in telehealth's effectiveness across different outpatient services as some conditions may necessitate in-person physical examination or diagnostic testing.[359] [360] There are also known disparities in the effectiveness of telehealth and its impact on outcomes as certain populations lack access to internet and digital devices, or lack familiarity with technology.[361] [362]

For the Hospital OQR Program, we are considering a measure focused on telehealth quality based on a framework developed by the CBE.[363] This framework was chosen because it offers a comprehensive guide for developing telehealth measures under four domains: access, effectiveness, experience, and equity. We seek input from interested parties on the following topics: (1) inclusion and prioritization of areas of telehealth-related care, and in particular those priority topic areas discussed above; (2) addressing quality gaps in outpatient telehealth-related care, including across HOPD settings and services; (3) capturing utilization, and disparities resulting from

[348] Stone DM, Simon TR, Fowler KA, et al. (2018) Vital Signs: Trends in State Suicide Rates—United States, 1999–2016 and Circumstances Contributing to Suicide—27 States, 2015. *MMWR*, 67, 617–624. *http://dx.doi.org/10.15585/mmwr.mm6722a1.*

[349] Boudreaux ED, Camargo CA, Arias SA, et al. (2016). Improving Suicide Risk Screening and Detection in the Emergency Department. *American Journal of Preventive Medicine*, 50(4), 445–453. *https://doi.org/10.1016/j.amepre.2015.09.029.*

[350] Substance Abuse and Mental Health Services Administration. (2021).

Table 5.1B—Substance Use Disorder for Specific Substances in Past Year: Among People Aged 12 or Older; by Age Group, Percentages, 2021. Available at: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39441/NSDUHDetailedTabs2021/NSDUHDetailedTabs2021/NSDUHDetTabs Sect5pe2021.htm.*

[351] Substance Abuse and Mental Health Services Administration. (2022). Screening, Brief Intervention, and Referral to Treatment (SBIRT). Available at: *https://www.samhsa.gov/sbirt.*

[352] O'Connor EA, Perdue LA, Senger, CA, et al. (2018). Screening and Behavioral Counseling Interventions to Reduce Unhealthy Alcohol Use in Adolescents and Adults: Updated Evidence Report and Systematic Review for the US Preventive Services Task Force. JAMA, 320(18), 1910–1928. *https://doi.org/10.1001/jama.2018.12086.*

[353] Telehealth Services, 42 CFR 410.78 Available at: *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.78.*

[354] Corbett, JA, Opladen, JM, & Bisognano, JD. (2020). Telemedicine can revolutionize the treatment of chronic disease. *International Journal of Cardiology. Hypertension*, 7, 100051. *https://doi.org/10.1016/j.ijchy.2020.100051.*

[355] American Health Association. (2016). Telehealth: Helping Hospitals Deliver Cost-Effective Care. Available at: *https://www.aha.org/system/files/content/16/16telehealthissuebrief.pdf.*

[356] Patel KB, Turner K, Alishahi TA, et al. (2023). Estimated Indirect Cost Savings of Using Telehealth Among Nonelderly Patients With Cancer. *JAMA network open*, 6(1), e2250211. *https://doi.org/10.1001/jamanetworkopen.2022.50211.*

[357] Lo, J, Rae M, Amin, K, & Cox C. (2022). Outpatient telehealth use soared early in the COVID–19 pandemic but has since receded. *Peterson-KFF Health System Tracker.* Available at: *https://www.healthsystemtracker.org/brief/outpatient-telehealth-use-soared-early-in-the-covid-19-pandemic-but-has-since-receded/.*

[358] Ibid.

[359] Patel SY, Mehrotra A, Huskamp HA, et al. (2021). Variation in Telemedicine Use and Outpatient Care During The COVID–19 Pandemic in the United States. *Health affairs (Project Hope)*, 40(2), 349–358. *https://doi.org/10.1377/hlthaff.2020.01786.*

[360] Koonin LM, Hoots B, Tsang CA, et al. Trends in the Use of Telehealth During the Emergence of the COVID–19 Pandemic—United States, January–March 2020. *MMWR Morb Mortal Wkly Rep* 2020;69:1595–1599. *http://dx.doi.org/10.15585/mmwr.mm6943a3.*

[361] Ibid.

[362] Roberts ET, & Mehrotra A. (2020). Assessment of Disparities in Digital Access Among Medicare Beneficiaries and Implications for Telemedicine. *JAMA internal medicine*, 180(10), 1386–1389. *https://doi.org/10.1001/jamainternmed.2020.2666.*

[363] National Quality Forum. (2021). Rural Telehealth and Healthcare System Readiness Measurement Framework—Final Report. Available at: *https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework_-_Final_Report.aspx.*

utilization, of telehealth-related care for outpatient settings and services; and (4) understanding patient experience with outpatient telehealth services. Specifically, we are requesting comment from interested parties on the following questions:

- In reference to the telehealth-related topics outlined above, are there additional matters that we should prioritize for the Hospital OQR Program? Which subjects are of the highest priority?
- What do commenters believe are the most relevant clinical issues addressable through telehealth in outpatient settings, and gaps in care that telehealth can address?
- What are the highest priority concerns regarding disparities in access, use, or outcomes related to telehealth in the outpatient setting? Are there any settings or services that should be prioritized?
- Which existing outpatient quality measures should be stratified by telehealth as the mode of delivery?
- What are the most relevant patient-experience-related telehealth outcomes that should be measured?

D. Administrative Requirements

1. Proposal To Modify Requirements Regarding Hospital OQR Program Participation Status

We refer readers to § 419.46(b) for our current policies regarding participation in the Hospital OQR Program, including security official and system registration requirements. We propose to amend our participation regulation codified at § 419.46(b)(1) and (2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

2. Proposal To Modify Requirements Regarding Hospital OQR Program Withdrawal

We refer readers to § 419.46(c) for our policies regarding requirements for withdrawal from the Hospital OQR Program. We propose to amend our withdrawal policy codified at § 419.46(c) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(c), we are not proposing any changes to these policies in this proposed rule.

E. Form, Manner, and Timing of Data Submitted for the Hospital OQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938–1109 (expiration date February 28, 2025).[364] An updated PRA package reflecting the updated information collection requirements related to the proposals set forth in this section of the proposed rule will be submitted for approval under the same OMB control number.

1. Hospital OQR Program Annual Submission Deadlines

We refer readers to § 419.46(d) for our policies regarding clinical data submission deadlines. In the CY 2023 OPPS/ASC final rule (87 FR 72110 through 72112), we finalized alignment of the patient encounter quarters for chart-abstracted measures with the calendar year beginning with the CY 2024 reporting period/CY 2026 payment determination. To facilitate this process, we finalized transitioning to the new timeframe for the CY 2026 payment determination and subsequent years and use only three quarters of data for chart-abstracted measures in determining the CY 2025 payment determination as illustrated in the Tables 68, 69, and 70 below (87 FR 44734).

BILLING CODE 4120–01–P

TABLE 68: CY 2024 Payment Determination* (Current state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2022 (April 1 - June 30)	11/1/2022**
Q3 2022 (July 1 – September 30)	2/1/2023**
Q4 2022 (October 1 - December 31)	5/1/2023**
Q1 2023 (January 1 - March 31)	8/1/2023**

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.

**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

[364] Office of Management and Budget. Office of Information and Regulatory Affairs. Available at: *https://www.reginfo.gov/public/do/PRAOMBHistory?ombControlNumber=0938-1109.*

TABLE 69: Finalized CY 2025 Payment Determination*(Future state—transition period)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q2 2023 (April 1 - June 30)	11/1/2023**
Q3 2023 (July 1 – September 30)	2/1/2024**
Q4 2023 (October 1 - December 31)	5/1/2024**

* All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

TABLE 70: Finalized CY 2026 Payment Determination* (Future state)

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 - March 31)	8/1/2024**
Q2 2024 (April 1 - June 30)	11/1/2024**
Q3 2024 (July 1 – September 30)	2/1/2025**
Q4 2024 (October 1 - December 31)	5/1/2025**

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or Executive order would be extended to the first day thereafter.
**The August 1st, November 1st, February 1st, and May 1st deadlines are recurring.

BILLING CODE 4120–01–C

We propose to amend our submission deadline codified at § 419.46(d)(2) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(d)(2), we are not proposing any changes to these policies in this proposed rule.

2. Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68481 through 68484) and the CMS website, currently available at: *https://qualitynet.cms.gov*, for a discussion of the requirements for chart-abstracted measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2014 payment determination and subsequent years.

We are not proposing any changes to these policies in this proposed rule.

3. Claims-Based Measure Data Requirements

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59106 through 59107), where we established a 3-year reporting period for the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure beginning with the CY 2020 payment determination. We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63863) where we finalized a 3-year reporting period for the Breast Cancer Screening Recall Rates measure.

We are not proposing any changes to these policies in this proposed rule.

4. Data Submission Requirements for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey-Based Measure

We refer readers to the CYs 2017, 2018, and 2022 OPPS/ASC final rules (81 FR 79792 through 79794; 82 FR 59432 and 59433; and 86 FR 63863 through 63866, respectively) for a discussion of the previously finalized requirements related to survey administration and vendors for the OAS CAHPS Survey-based measure. For more information about the modes of administration, we refer readers to the OAS CAHPS Survey website: *https://oascahps.org/*.

We are not proposing any changes to these policies in this proposed rule.

5. Data Submission Requirements for Measures Submitted via a Web-Based Tool

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75112 through 75115), the CY 2016 OPPS/ASC final rule (80 FR 70521), and the CMS website, currently at available at *https://qualitynet.cms.gov*, for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The information collections finalized in the aforementioned final rules were approved under OMB control number 0938–1109 (expiration date February 28, 2025).[365] The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information.

We are not proposing any changes to these policies in this proposed rule.

[365] Ibid.

b. Proposed HOPD Procedure Volume Measure Reporting and Data Submission Requirements

We propose to re-adopt the HOPD Procedure Volume measure with modification, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We propose that hospitals submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting period, the submission period to report the data to CMS through the HQR System would be January 1, 2026 to May 15, 2026, covering the performance period of January 1, 2025 to December 31, 2025. Following a 30-day preview period, CMS would publicly display data surrounding the top five most frequently performed procedures among HOPDs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[366] This data would be publicly displayed on the Care Compare website or another CMS website. We would assess and update the top five procedures in each category annually, as needed. We propose that hospitals would submit aggregate-level data through the CMS Web-based tool within the HQR System. We refer readers to the CY 2009, CY 2014, and CY 2017 OPPS/ASC final rules (73 FR 68777 through 68779, 78 FR 75092, and 81 FR 79791, respectively) for our previously finalized policies regarding public display of quality measures. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invite public comment on this proposal.

c. Proposed Modification of Survey Instrument Use for the Cataracts Visual Function Measure Reporting and Data Submission Requirements

In section XIV.B.2.b of this proposed rule, we propose to modify the Cataracts Visual Function measure survey instrument use, beginning with the voluntary CY 2024 reporting period. The proposed modified measure would refine data collection by standardizing survey instruments that HOPDs can use, which would limit the allowable survey instruments to those listed below:

The National Eye Institute Visual Function Questionnaire–25 (NEI VFQ–25)

The Visual Functioning Patient Questionnaire (VF–14)

The Visual Functioning Index Patient Questionnaire (VF–8R)

We also propose that hospitals submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the voluntary CY 2024 reporting period, the data submission period would be January 1, 2025 to May 15, 2025, covering the performance period of January 1, 2024 to December 31, 2024. Specifically, for data collection, we propose that hospitals submit aggregate-level data through the CMS Web-based tool within the HQR System. We previously codified our existing policies regarding data collection and submission under the Hospital OQR Program at § 419.46.

We invite public comment on this proposal.

d. Data Submission Requirements for Measures Submitted via the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Website

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75097 through 75100) for a discussion of the previously finalized requirements for measure data submitted via the CDC NHSN website. In addition, we refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63866), where we finalized the adoption of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2022 reporting period/CY 2024 payment determination. In section XIV.B.2.a of this proposed rule, we discuss the proposed modification of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website would remain as previously finalized.

We are not proposing any changes to these policies in this proposed rule.

6. eCQM Reporting and Submission Requirements

a. Background

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75106 and 75107), the CY 2015 OPPS/ASC final rule (79 FR 66956 through 66961), the CY 2016 OPPS/ASC final rule (80 FR 70516 through 70518), the CY 2017 OPPS/ASC final rule (81 FR 79785 through 79790), the CY 2018 OPPS/ASC final rule (82 FR 59435 through 59438), the CY 2022 OPPS/ASC final rule (86 FR 63867 through 63870), and the CY 2023 OPPS/ASC final rule (87 FR 72113 through 72114) for more details on previous discussion regarding future measure concepts related to eCQMs and electronic reporting of data for the Hospital OQR Program, including support for the introduction of eCQMs into the Program.

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63867 through 63868), where we finalized the adoption of the STEMI eCQM reporting and data submission requirements. For the CY 2024 reporting period/CY 2026 payment determination, hospitals must submit one self-selected quarter of data.

We are not proposing any changes to these policies in this proposed rule.

b. Proposed Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM Reporting and Data Submission Requirements

In section XIV.B.3.c of this proposed rule, we discuss the proposed adoption of the Excessive Radiation eCQM beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. In this proposed rule, we propose a progressive increase in the number of quarters for which hospitals report eCQM data. We propose that hospitals that submit Excessive Radiation eCQM data during the CY 2025 voluntary period may submit up to all four quarter(s) of data.

Beginning with the CY 2026 mandatory reporting period/CY 2028 payment determination, we propose that hospitals report two self-selected calendar quarters of data for the Excessive Radiation eCQM. Beginning with the CY 2027 reporting period/CY 2029 payment determination, we propose to require hospitals to report all four calendar quarters (one calendar year) of data for the Excessive Radiation eCQM. We believe that a phased implementation approach would allow facilities the ability to make the necessary adjustments for data submission over time and would produce more comprehensive and reliable quality measure data for patients and providers. Furthermore, we believe that aligning the schedule with the STEMI measure will allow for a seamless transition from voluntary to mandatory reporting of all calendar quarters.

[366] Centers for Medicare & Medicaid Services. (2016). Hospital Outpatient Specifications Manuals version 9.1. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals#tab9.*

We also refer readers to Table 71 for a summary of the proposed quarterly data increase in eCQM reporting beginning with the CY 2025 reporting period.

TABLE 71: Proposed Progressive Increase in eCQM Reporting Beginning with the CY 2025 Reporting Period and for Subsequent Years

Calendar Year Period	Calendar Quarters of Reporting	Reporting Requirement
CY 2025 Reporting Period	Any quarter(s)	Voluntary
CY 2026 Reporting Period/CY 2028 Payment Determination	Two self-selected quarters	Mandatory
CY 2027 Reporting Period/CY 2029 Payment Determination	Four quarters (one calendar year)	Mandatory

We also propose to require Excessive Radiation eCQM data submission by May 15 in the year prior to the affected payment determination year. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive Order would be extended to the first day thereafter. For example, for the CY 2026 reporting period/CY 2028 payment determination, hospitals must report two self-selected quarters of data and would be required to submit eCQM data by May 15, 2027. This data submission deadline would follow our policies on submission deadlines for eCQM data defined in section XIV.E.6.e of this proposed rule.

We invite public comment on our proposals.

c. Electronic Clinical Quality Measure Certification Requirements for eCQM Reporting

(1) Use of the 2015 Edition Cures Update Certification Criteria

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63868 and 63869) for our policies regarding the requirement that hospitals participating in the Hospital OQR Program utilize certified technology updated consistent with the 2015 Edition Cures Update as finalized in the Office of the National Coordinator for Health Information Technology (ONC) 21st Century Cures Act final rule (85 FR 25642 through 25961) beginning with the CY 2023 reporting period/CY 2025 payment determination.

We are not proposing any changes to these policies in this proposed rule.

d. File Format for eCQM Data, Zero Denominator Declarations, and Case Threshold Exemptions

(1) File Format for eCQM Data

We refer reader to the CY 2022 OPPS/ASC final rule (86 FR 42262) for our policies regarding the file format for eCQM data.

We are not proposing any changes to these policies in this proposed rule.

(2) Zero Denominator Declarations

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63869) for our policies regarding zero denominator declarations.

We are not proposing any changes to these policies in this proposed rule.

(3) Case Threshold Exemptions

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63869) for our policies regarding case threshold exemptions.

We are not proposing any changes to these policies in this proposed rule.

e. Submission Deadlines for eCQM Data

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) for our policies regarding submission deadlines for eCQM data.

We are not proposing any changes to these policies in this proposed rule.

7. Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In section XIV.B.3.b of this proposed rule, we propose the adoption of the hospital-level THA/TKA PRO–PM into the Hospital OQR Program measure set. In this section of the proposed rule, we propose the reporting and submission requirements for PRO–PM as a new type of measure to the Hospital OQR Program.

a. Submission of PRO–PM Data

(1) Data Submission Generally

In section XIV.B.3.b of this proposed rule, we propose adoption of the THA/TKA PRO–PM in the Hospital OQR Program beginning with voluntary CYs 2025 and 2026 reporting periods and mandatory reporting period beginning with the CY 2027/CY 2030 payment determination. We propose that hospitals and vendors use the HQR System for data submission for the THA/TKA PRO–PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. HOPDs may choose to: (1) send their data to CMS directly; or (2) utilize an external entity, such as through a vendor or registry, to submit data on behalf of the facility to CMS. We would provide hospitals with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, through outreach, or both. Use of the HQR system leverages existing CMS infrastructure already utilized for other quality measures. The HQR System allows for data submission using multiple file formats (such as CSV, XML) and a manual data entry option, allowing facilities and vendors additional flexibility in data submission.

(2) Data Submission Reporting Requirements

(a) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

For hospitals participating in voluntary reporting for the THA/TKA PRO–PM as discussed in section

XIV.B.3.b of this proposed rule, we propose that hospitals submit pre-operative PRO data, as well as matching post-operative PRO data, for at least 50 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO–PM, we propose that the first voluntary reporting period for CY 2025 would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025, through December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during the first voluntary reporting period for CY 2025, hospitals would submit pre-operative data by May 15, 2026 and post-operative data by May 15, 2027, and we intend to provide hospitals with their results in confidential feedback reports in CY 2028. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive order would be extended to the first day thereafter. After the initial submission of pre-operative data for the first voluntary period, hospitals would submit both pre-operative data for the second voluntary period and post-operative data for the first voluntary period by the same data submission deadline, but for the different voluntary reporting periods. For example, hospitals would need to submit: (1) post-operative data for the first voluntary reporting (for procedures performed between January 1, 2025, and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026, and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

For the THA/TKA PRO–PM, we propose that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026 through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. Hospitals would submit pre-operative data for the second voluntary reporting period by May 15, 2027 and post-operative data for the second voluntary reporting period by May 15, 2028.we intend to provide hospitals with their results in confidential feedback reports in CY 2029. HOPDs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating facility with their RSIR as part of the confidential feedback reports. This would provide each facility with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we do not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO–PM facility-level RSIR, we propose to publicly report which facilities choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating facilities for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that the facility submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 72 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 72: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM VOLUNTARY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview/ Public Reporting
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-February 28, 2027	May 15, 2027*	CY 2028
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027	October 28, 2026-February 28, 2028	May 15, 2028	CY 2029

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive Order would be extended to the first day thereafter.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CY 2025 reporting period and CY 2029 for the CY 2026 reporting period.

(b) Mandatory Reporting

Following the voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027 through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026 through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027 through December 31, 2027) and post-operative PRO data collection from October 28, 2027 to February 28, 2029. Pre-operative data submission would occur by May 15, 2028 and post-operative data submission would occur by May 15, 2029.

We intend to provide hospitals with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare*, or its successor website. We would provide confidential feedback reports during the voluntary period which would include the risk-standardized improvement rate (RSIR); as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, hospitals that fail to meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in the CY 2030 payment determination. We propose that hospitals would be required to submit 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the Hospital OQR Program.

We refer readers to Table 73 below. for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first year of mandatory reporting.

TABLE 73: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO–PM FOR MANDATORY REPORTING

Reporting Cycle	THA/TKA Procedures Performed	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Preview and Public Reporting
Mandatory Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	2030*

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive order would be extended to the first day thereafter.

*Public reporting of information on facility results in the Mandatory Reporting periods would occur in CY 2030 for CY 2027 reporting period/CY2030 payment determination.

We invite comment on these proposals.

8. Population and Sampling Data Requirements for the CY 2023 Payment Determination and Subsequent Years

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72100 through 72103) and the CY 2012 OPPS/ASC final rule (76 FR 74482 through 74483) for our policies regarding population and sampling data requirements.

We are not proposing any changes to these policies in this proposed rule.

9. Review and Corrections Period for Measure Data Submitted to the Hospital OQR Program

a. Chart-Abstracted Measures

We refer readers to the CY 2015 OPPS/ASC final rule (79 FR 66964 and 67014) for our policies regarding a review and corrections period for chart-abstracted measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

b. Web-Based Measures

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86184) for our policies regarding a review and corrections period for web-based measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

c. Electronic Clinical Quality Measures (eCQMs)

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) for our policies regarding a review and corrections period for eCQMs in the Hospital OQR Program. We refer readers to the CMS website (currently available at: *https://qualitynet.cms.gov/outpatient/measures/eCQM*) and the eCQI Resource Center (available at: *https://ecqi.healthit.gov/*) for more resources on eCQM reporting.

We are not proposing any changes to these policies in this proposed rule.

d. OAS CAHPS Measures

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) and the CY 2017 OPPS/ASC final rule (81 FR 79793) for our policies regarding a review and corrections period for OAS CAHPS measures in the Hospital OQR Program.

We are not proposing any changes to these policies in this proposed rule.

10. Hospital OQR Program Validation Requirements

a. Background

We refer readers to the CY 2011 OPPS/ASC final rule (75 FR 72105 through 72106), the CY 2013 OPPS/ASC final rule (77 FR 68484 through 68487), the CY 2015 OPPS/ASC final rule (79 FR 66964 through 66965), the CY 2016 OPPS/ASC final rule (80 FR 70524), the CY 2018 OPPS/ASC final rule (82 FR 59441 through 59443), the CY 2022 OPPS/ASC final rule (86 FR 63870 through 63873), the CY 2023 OPPS/ASC final rule (87 FR 72115 through 72116), and § 419.46(f) for our policies regarding validation.

We are not proposing any changes to these policies in this proposed rule.

b. Use of Electronic File Submissions for Chart-Abstracted Measure Medical Records Requests

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63870) for additional information on the use of electronic file submissions for chart-abstracted measure medical records requests.

We are not proposing any changes to these policies in this proposed rule.

c. Time Period for Chart-Abstracted Measure Data Validation

We refer readers to the chart-abstracted validation requirements and methods we adopted in the CY 2014 OPPS/ASC final rule (78 FR 75117 through 75118) and codified at § 419.46(f)(1) for the CY 2025 payment determination and subsequent years. We refer readers to § 419.46(f)(1) for our policies regarding the time period for chart-abstracted measure data validation.

We are not proposing any changes to these policies in this proposed rule.

d. Targeting Criteria

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74485), where we finalized a validation selection process in which we select a random sample of 450 hospitals for validation purposes and select an additional 50 hospitals based on specific criteria; the CY 2013 OPPS/ASC final rule (77 FR 68485 and 68486), where we finalized that a hospital will be preliminarily selected for validation based on targeting criteria if it fails the validation requirement that applies to the previous year's payment determination, and for a discussion of finalized policies regarding our medical record validation procedure requirements; the CY 2018 OPPS/ASC final rule (82 FR 59441), where we clarified that an ''outlier value'' for purposes of the targeting criterion; the CY 2022 OPPS/ASC final rule (86 FR 63872), where we finalized the addition of two targeting criteria: (1) any hospital that has not been randomly selected for validation in any of the previous three years; or (2) any hospital that passed validation in the previous year and had a two-tailed confidence interval that included 75 percent; and the CY 2023 OPPS/ASC final rule (87 FR 72115 through 72116), where we finalized an additional targeting criteria: any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters. We refer readers to § 419.46(f)(3) for our policies regarding the validation selection process and targeting criteria.

We are not proposing any changes to these policies in this proposed rule.

e. Educational Review Process and Score Review and Correction Period for Chart-Abstracted Measures

We refer readers to § 419.46(f)(4) for our policies regarding the educational review process, including validation score review and correction, for chart-abstracted measures.

We are not proposing any changes to these policies in this proposed rule.

11. Extraordinary Circumstances Exception (ECE) Process

We refer readers to § 419.46(e) for our policies regarding the extraordinary circumstances exception (ECE) process under the Hospital OQR Program. We propose to amend our exception policy codified at § 419.46(e)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website.'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(e)(1), we are not proposing any changes to these policies in this proposed rule.

12. Hospital OQR Program Reconsideration and Appeals Procedures

We refer readers to § 419.46(g) for our policies regarding reconsideration and appeals procedures. We propose to amend our submission deadline codified at § 419.46(g)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

Other than the proposal to amend § 419.46(g)(1), we are not proposing any changes to these policies in this proposed rule.

F. Payment Reduction for Hospitals That Fail To Meet the Hospital OQR Program Requirements for the CY 2024 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0 percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the internet on the CMS website): ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', or ''U''. In the CY 2017 OPPS/ASC final

rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator ''Q4'' because services and procedures coded with status indicator ''Q4'' are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS. Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator ''S'' or ''T''. We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the ''reporting ratio'' to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor − 0.02)

Reporting Ratio = Reduced Conversion Factor/Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor − 0.02)/(1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria, we refer readers to section II.G of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2024

We proposed to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2024 annual payment update factor. For this CY 2024 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $87.488, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.782. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of ''J1'', ''J2'', ''P'', ''Q1'', ''Q2'', ''Q3'', ''R'', ''S'', ''T'', ''V'', and ''U'' (other than New Technology APCs to which we have proposed status indicator assignments of ''S'' and ''T''). We proposed to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our

proposal to implement the policy through the use of a reporting ratio, we also propose to calculate the reporting ratio to four decimals (rather than the previously used three decimals) to more precisely calculate the reduced adjusted payment and copayment rates.

For CY 2024, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $87.488, equaled a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $85.782.

XV. Ambulatory Surgical Center Quality Reporting (ASCQR) Program Requirements, Proposals, and Requests for Comment

A. Background

1. Overview

We seek to promote higher quality, more efficient, and equitable healthcare for Medicare beneficiaries. Consistent with these goals, we have implemented quality reporting programs for multiple care settings, including the Ambulatory Surgical Center Quality Reporting (ASCQR) Program for ambulatory surgical center care.

2. Statutory Authority for the ASCQR Program

Section 1833(i)(7)(A) authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0 percentage points for such year that an ASC that fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, several of the statutory provisions governing the Hospital Outpatient Quality Reporting (OQR) Program, specifically section 1833(t)(17)(B) through (E) of the Act, also apply to the services of ASCs under the ASCQR Program in a similar manner to the manner in which they apply to the services of hospital outpatient departments under the Hospital OQR Program. Sections 1833(t)(17)(B) through (E) of the Act generally govern the development and replacement of quality measures, the form and manner of submission of data to CMS, and procedures for making the data submitted to CMS available to the public.

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASCQR Program.

3. Regulatory History of the ASCQR Program

We refer readers to the following final rules for detailed discussions of the regulatory history of the ASCQR Program:

- CY 2012 OPPS/ASC final rule (76 FR 74492 through 74517);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53637 through 53644);
- CY 2013 OPPS/ASC final rule (77 FR 68492 through 68500);
- CY 2014 OPPS/ASC final rule (78 FR 75122 through 75141);
- CY 2015 OPPS/ASC final rule (79 FR 66966 through 66987);
- CY 2016 OPPS/ASC final rule (80 FR 70526 through 70538);
- CY 2017 OPPS/ASC final rule (81 FR 79797 through 79826);
- CY 2018 OPPS/ASC final rule (82 FR 59445 through 59476);
- CY 2019 OPPS/ASC final rule (83 FR 59110 through 59139);
- CY 2020 OPPS/ASC final rule (84 FR 61420 through 61434);
- CY 2021 OPPS/ASC final rule (85 FR 86187 through 86193);
- CY 2022 OPPS/ASC final rule (86 FR 63875 through 63911); and
- CY 2023 OPPS/ASC final rule (87 FR 72117 through 72136)

We have codified certain requirements under the ASCQR Program at 42 CFR part 416, subpart H (§ 416.300 through § 416.330). We refer readers to section XV.E of this proposed rule for a detailed discussion of the payment reduction for ASCs that fail to meet program requirements.

B. ASCQR Program Quality Measures

1. Considerations in the Selection of ASCQR Program Quality Measures

We refer readers to the CY 2013 OPPS/ASC final rule (77 FR 68493 and 68494) for a detailed discussion of the priorities we consider for quality measure selection for the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

2. Retention of Previously Adopted ASCQR Program Measures

We previously finalized and codified at § 416.320(a) our policy regarding retention of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(a) provides that we will retain quality measures previously adopted for the ASCQR Program as part of its measure set unless we remove, suspend, or replace the measure.

We are not proposing any changes to this policy in this proposed rule.

3. Removal, Replacement, or Suspension of Quality Measures From the ASCQR Program Measure Set

a. Immediate Removal of Program Measures

We refer readers to § 416.320(b) for our policies regarding immediate removal of a measure for the ASCQR Program based on evidence that the continued use of the measure as specified raises patient safety concerns. We propose to amend our measure removal policy codified at § 416.320(b) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

b. Removal, Replacement, or Suspension of Program Measures

We previously finalized and codified at § 416.320(c) our policies regarding removal of quality measures adopted for the ASCQR Program. Specifically, our regulation at § 416.320(c) provides that, unless a measure raises specific safety concerns, we will use the regular rulemaking process, allowing public comment, to remove, suspend, or replace quality measures in the ASCQR Program. Our regulation at § 416.320(c)(2) further provides that we will weigh whether to remove measures based on eight factors, including whether a measure is ''topped-out'' (§ 416.320(c)(2)(i)), based on criteria set forth in our regulation at § 416.320(c)(3). However, as provided in our regulation at § 416.320(c)(4), we will assess the benefits of removing a measure on a case-by-case basis and will not remove a measure solely on the basis of it meeting any of specific factor or criterion.

We are not proposing any changes to these policies in this proposed rule.

4. Modifications to Previously Adopted Measures

In this proposed rule, we propose to modify three previously adopted measures beginning with the CY 2024 reporting period/CY 2026 payment determination: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure; (2) Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument use; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for

Normal Colonoscopy in Average Risk Patients measure.

a. Proposed Modification of the COVID–19 Vaccination Coverage Among HealthCare Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services (HHS) declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–COV–2, a then novel coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[367] Subsequently, the COVID–19 Vaccination Coverage Among Health Care Personnel (HCP) measure was adopted across multiple quality reporting programs, including the ASCQR Program (86 FR 63875 through 63833).[368] COVID–19 has continued to spread domestically and around the world with more than 102.7 million cases and 1.1 million deaths in the United States alone as of February 13, 2023.[369] The Secretary renewed the PHE on April 21, 2020 and then every three months thereafter, with the final renewal on February 9, 2023.[370] The PHE ended on May 11, 2023; however, the public health response to COVID–19 remains a public health priority including vaccination efforts.[371]

As stated in the CY 2022 OPPS/ASC final rule (86 FR 63876) and in our ''Revised Guidance for Staff Vaccination Requirements,'' vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19.[372] [373] [374] We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the ASC setting, 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. Studies indicate higher levels of population-level vaccine effectiveness in preventing COVID–19 infection among HCP and other frontline workers in multiple industries, with vaccines having a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[375] Since the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) for selected initial and primary vaccines for adults, vaccines have been highly effective in real-world conditions at preventing COVID–19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[376] [377] [378] [379] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, hospitalization, and death from the COVID–19 infection.[380]

When we adopted the COVID–19 Vaccination Coverage Among HCP measure in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we acknowledged that the measure did not address booster shots for COVID–19 vaccination (86 FR 63881), although the FDA authorized, and the Centers for Disease Control and Prevention (CDC) recommended, additional doses and booster doses of the COVID–19 vaccine for certain individuals, particularly those who are immunocompromised due to age or condition or who are living or working in high-risk settings, such as HCP (86 FR 63881). However, we also stated that we believed the numerator of the measure was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' (86 FR 63881).

Since then, 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.[381] 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.[382] Booster doses of the bivalent COVID–19 vaccine have proven effective at increasing immune response to SARS–COV–2 variants, including Omicron, particularly in individuals

[367] 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*.

[368] The Hospital Inpatient Quality Reporting Program (86 FR 45374 through 45382), the Hospital OQR Program (86 FR 63824 through 63833), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), 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), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396).

[369] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed February 13, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home*.

[370] 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*.

[371] 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*.

[372] Centers for Medicare & Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/revised-guidance-staff-vaccination-requirements*.

[373] 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://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w*.

[374] Centers for Medicare & Medicaid Services. (2022). Revised Guidance for Staff Vaccination Requirements. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[375] 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 at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm*.

[376] Pilishivi T, Gierke R, Fleming-Dutra KE, et al. (2022). Effectiveness of mRNA Covid–19 Vaccine among U.S. Health Care Personnel. *New England Journal of Medicine*, 385(25), e90. *https://doi.org/10.1056/NEJMoa2106599*.

[377] Centers for Disease Control and Prevention. (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*.

[378] Centers for Medicare & Medicaid Services. (2022). Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[379] Food and Drug Administration. (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*.

[380] 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/*.

[381] Centers for Disease Control and Prevention. (August 2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*.

[382] Food and Drug Administration. (November 2022). COVID–19 Bivalent Vaccine Boosters. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines*.

who are more than six months removed from receipt of their primary series.[383] These booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only the two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[384] [385] Data from the existing COVID–19 Vaccination Coverage Among HCP measure demonstrate clinically significant variation in booster dose vaccination rates across ASCs.

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, we believe it is important to modify the COVID–19 Vaccination Coverage Among HCP measure for HCP to receive primary series and booster vaccine doses in a timely manner per the CDC's recommendation that bivalent COVID–19 vaccine booster doses might improve protection against SARS–CoV–2 Omicron sublineages.[386]

We propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition. We also propose to update the numerator to specify the timeframes within which an HCP is considered up to date with CDC recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program.

We note that as we stated in the CY 2022 OPPS/ASC final rule (86 FR 63877), the COVID–19 Vaccination Coverage Among HCP measure is a process measure that assesses HCP vaccination coverage rates and not an outcome measure for which ASCs are held responsible for a particular outcome. We propose to adopt the same modification to versions of the measure that we have adopted for other quality reporting programs.[387]

(2) Overview of 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 various settings. ASCs report the required data for this measure via the CDC's National Healthcare Safety Network (NHSN). We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63877 through 63878) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).[388]

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, during the MAP's Hospital Workgroup discussion, the workgroup stated that the revision of the current measure captures up to date vaccination information in accordance with the CDC's updated recommendations for additional and booster doses since the measure's initial development. Additionally, the Hospital Workgroup appreciated that the revised measure's target population is broader and simplified from seven categories of HCP to four.[389] During the MAP's Health Equity Advisory Group review, the group highlighted the importance of COVID–19 vaccination measures and questioned whether the proposed revised version of the measure excludes individuals with contraindications to FDA authorized or approved COVID–19 vaccines, and if the measure would be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but stated that 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.[390] We note that when reviewed by the MAP, reporting for contract personnel providing care or services not specifically included in the measure denominator was fully optional, whereas this reporting is now required to complete NHSN data entry, but is not included in the measure calculation. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage Among HCP measure (CBE #0431).[391] We refer readers to sections XXIV.B and XXVI (Collection of Information) of this proposed rule for additional detail on the burden and impact of this proposal.

The proposed revised measure received conditional support for rulemaking from the MAP pending (1) testing indicating the measure is reliable and valid, and (2) endorsement by the consensus-based entity (CBE). The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636) [392] and that the measure steward (CDC) intends to submit the updated measure for endorsement.[393]

(a) Measure Specifications

This measure is calculated quarterly by averaging the ASC's most recently submitted and self-selected one week of data. The measure includes at least 1 week of data collection a month for each of the three months in a quarter. The

[383] Chalkias, S et al. (October 2022). A Bivalent Omicron-Containing Booster Vaccine against Covid–19. N Engl J Med 2022; 387:1279–1291. Available online at: *https://www.nejm.org/doi/full/10.1056/NEJMoa2208343*.

[384] 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/*.

[385] 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/*.

[386] Centers for Medicare and Medicaid Services. (October 26, 2022). Revised Guidance for Staff Vaccination Requirements. Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[387] The Hospital Inpatient Quality Reporting Program, the Long-Term Care Hospital Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program (88 FR 27074) as well as the Inpatient Psychiatric Facility Quality Reporting Program (88 FR 21290), the Skilled Nursing Facility Quality Reporting Program (88 FR 21332), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244),), and the Inpatient Rehabilitation Facility Quality Reporting Program (88 FR 20985).

[388] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[389] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[390] Ibid.

[391] In previous years, we referred to the consensus-based entity (CBE) by corporate name. We have updated this language to refer to the CBE more generally.

[392] Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11670&sectionNumber=1*.

[393] The measure steward owns and maintains a measure while a measure developer develops, implements, and maintains a measure. In this case, the CDC serves as both the measure steward and measure developer. For more information on measure development, we refer readers to: Centers for Medicare and Medicaid Services (2023). Roles in Measure Development. Available at: *https://mmshub.cms.gov/about-quality/new-to-measures/roles*.

denominator is calculated as the aggregated number of HCP eligible to work in the ASC for at least one day during the week of data collection, excluding denominator-eligible individuals with contraindications as defined by the CDC for all 3 months in a quarter.[394] Facilities report vaccination information for the following four, separate categories of HCP to NHSN:

- *Employees:* This includes all persons who receive a direct paycheck from the reporting facility (*i.e.,* on the facility's payroll), regardless of clinical responsibility or patient contact.
- *Licensed independent practitioners (LIPs):* This includes only physicians (MD, DO), advanced practice nurses, and physician assistants who are affiliated with the reporting facility, but are not directly employed by it (*i.e.,* they do not receive a 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.
- *Adult students/trainees and volunteers:* This includes medical, nursing, or other health professional students, interns, medical residents, or volunteers aged 18 or older who are affiliated with the facility but are not directly employed by it (*i.e.,* they do not receive a paycheck from the facility), regardless of clinical responsibility or patient contact.
- *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.[395] This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. We note that the other contract personnel category is required for data submission to NHSN, but is not included as part of the proposed COVID–19 Vaccination Coverage Among HCP measure.[396]

We are not proposing to modify the denominator exclusions. The numerator is calculated as the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccines. The term ''up to date'' is defined as meeting the CDC's set of criteria on the first day of the applicable reporting quarter. The current definition of ''up to date'' for COVID–19 vaccination can be found at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf.*

We refer readers to XV.D.1.c.(2) of this proposed rule for more details on the proposed modifications to this measure's specifications.

We propose that public reporting of the modified version of the COVID–19 Vaccination Coverage Among HCP for the ASCQR Program would begin with the Fall 2024 Care Compare refresh, or as soon as technically feasible.

(b) CBE Endorsement

The current version of the measure in ASCQR received CBE endorsement (CBE #3636) on July 26, 2022.[397] The measure steward (CDC) intends to pursue CBE endorsement for the modified version of this measure.

(3) Data Submission and Reporting

We refer readers to the CY 2022 OPPS/ASC final rule (86 FR 63879 through 63883) for information on data submission and reporting of this measure. While we are not proposing any changes to the data submission or reporting process, we propose that reporting of the updated, modified version of this measure would begin with the CY 2024 reporting period for the ASCQR Program. Under the data submission and reporting process, ASCs would collect the numerator and denominator for the COVID–19 Vaccination Coverage Among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline to meet ASCQR Program requirements. If an ASC submits more than one week of data in a month, the most recent week's data would be used to calculate the measure. For example, if first and third week data are submitted, the third week data would be used. Each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each ASC, which would be calculated by taking the average of the data from the three weekly rates submitted by the ASC for that quarter. CMS would publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (86 FR 63878).

We refer readers to section XIV.B.2.a of this proposed rule for the same proposal for the Hospital OQR Program.

We invite public comment on this proposal.

b. Proposed Modification of the Survey Instrument Used for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

(1) Background

In the CY 2014 OPPS/ASC final rule (78 FR 75129), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery (Cataracts Visual Function) measure beginning with the CY 2014 reporting period/CY 2016 payment determination. This measure assesses the percentage of patients aged 18 years and older who had cataract surgery and had improvement in visual function within 90 days following the cataract surgery via the administration of pre-operative and post-operative survey instruments (78 FR 75129). A ''survey instrument'' is an assessment tool that has been appropriately validated for the population for which it being used.[398] For purposes of this proposed modification to the Cataracts Visual Function measure, the survey instruments we considered and are proposing to assess the visual function of a patient pre- and post-operatively to determine whether the patient's visual function changed within 90 days of cataract surgery. Currently, examples of survey instruments assessing visual function include, but are not limited to, the National Eye Institute Visual Function Questionnaire (NEI–VFQ), the Visual Function (VF–14), the modified (VF–8R), the Activities of Daily Vision Scale (ADVS), the Catquest, and the modified Catquest-9. While the measure has been available for voluntary reporting in the ASCQR Program since the CY 2015 reporting period, a number of ASCs have reported data consistently using the survey instrument of their choice (87 FR 72119). We refer readers to the Cataracts Visual Function measure's Measure Information Form (MIF) and the ASCQR Program Specifications Manual for additional detail, which is available at: *https://*

[394] 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.*

[395] 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.*

[396] Ibid.

[397] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[398] Ambulatory Surgical Center Specification Manual. (n.d.). Qualitynet. Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals.*

qualitynet.cms.gov/asc/specifications-manuals.

In the CY 2015 OPPS/ASC final rule (79 FR 66984), we expressed concerns that clinicians' use of varying survey instruments would lead to inconsistent measure results. However, a study conducted a comparison among the 16 survey instruments currently accepted for use by ASCs in collecting data for this measure and found them to be scientifically validated, detected clinically important changes, and provided comparable results.[399] While all 16 survey instruments in this study demonstrate usefulness for detecting clinically important change in cataract patients, some survey instrument's detection sensitivity scores higher than others.[400]

Several commenters responding to the CY 2022 OPPS/ASC proposed rule (86 FR 63846) requested additional guidance from CMS regarding measure specifications and survey instruments for this Cataracts Visual Function measure in the Hospital OQR Program. We have considered this comment on this measure, and we agree that survey instruments for the assessment of visual function pre- and post-cataract surgery should be clarified in order to standardize acceptable survey instruments while minimizing collecting and reporting burden and to improve measure reliability. We propose to clarify which specific survey instruments may be used for the assessment of visual function pre- and post-cataract surgery for the Cataracts Visual Function measure in both the Hospital OQR Program and the ASCQR Program, to ensure alignment of this measure's specifications across our quality reporting programs. Thus, for the ASCQR Program, we propose to limit the survey instruments that an ASC may use to assess changes in a patient's visual function for purposes of the Cataracts Visual Function measure to those listed below:

- The National Eye Institute Visual Function Questionnaire–25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

(2) Considerations for the Standardization of Survey Instruments Assessing Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery

We took into consideration several factors when identifying which specific survey instruments would be acceptable for ASCs to use when collecting data for the Cataracts Visual Function measure, such as comprehensiveness, validity, reliability, length, and burden. We believe that these three proposed survey instruments will allow ASCs to select the length of the survey instrument to be administered while ensuring adequate validity and reliability.[401] [402] [403] All three of these proposed survey instruments are based upon the 51-item National Eye Institute Visual Function Questionnaire (NEI VFQ–51) survey instrument, which was the first survey instrument originally developed for assessing a patient's visual function before and after cataract surgery. Each of the three proposed survey instruments have progressively fewer numbers of questions than the NEI VFQ–51: 25 questions for the NEI VFQ–25, 14 questions for the VF–14, and 8 questions for the VF–8R. Even with fewer questions, all three of the proposed survey instruments have been validated as providing results comparable to the NEI VFQ–51. In addition, all three of the proposed survey instruments are readily available for ASCs to access and use.

We propose to allow ASCs to use the NEI VFQ–25 for administering and calculating this Cataracts Visual Function measure due to its comprehensiveness, its adequate validity and reliability, as well as its potential to reduce language barriers for patients. The NEI VFQ–25 is a shorter version of the NEI VFQ–51, being comprised of 25 items across 12 vision-specific domains (general health, general vision, ocular pain, near activities, distance activities, social functioning, mental health, role difficulties, dependency, driving, color vision, and peripheral vision).[404]

The NEI VFQ–25, similar to the VF–14 and VF–8R, has adequate reliability and validity.[405] The NEI VFQ–25 composite, near activities, and distance activities subscales demonstrated good internal consistency reliability, test-retest reliability, convergent validity, and known-groups validity.[406] Furthermore, the NEI VFQ–25's high internal consistency, indicates that items of the NEI VFQ–25 are highly related to each other and to the scale as a whole.[407]

In addition, the survey instrument is publicly available on the RAND website at no cost and has been translated to many languages, which is a valuable benefit for patients with limited English proficiency. The NEI VFQ–25 was chosen over other survey instruments to reduce potential language barriers, as, for example, the currently available Activities of Daily Vision Scale (ADVS) is dependent on English language skills.[408] More information on the NEI VFQ–25 can be found at: *https://www.rand.org/health-care/surveys_tools/vfq.html*.

While the NEI VFQ–25 was shortened significantly from the original NEI VFQ–51, it has been criticized for its still lengthy test-time. However, our proposal to include this survey instrument in this measure's specifications allows for a more detailed assessment of cataract surgery outcomes as it was designed to include questions which are most important for persons who have chronic eye diseases.[409] Further, if an ASC finds the NEI VFQ–25 particularly burdensome to administer, the ASC may choose from the other two survey instruments we propose for inclusion in this measure's

[399] McAlinden C, Gothwal VK, Khadka J, et al. (2011). A head-to-head comparison of 16 cataract surgery outcome questionnaires. *Ophthalmology*. 118(12):2374–81. *https://doi.org/10.1016/j.ophtha.2011.06.008*.

[400] Ibid.

[401] Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N.M., Kimel, M., Dolan, C., & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. American Journal of Ophthalmology, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006*.

[402] Hecht, I., Kanclerz, P., & Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

[403] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[404] U.S. Department of Health and Human Services. (n.d.). *Visual function questionnaire 25*. National Eye Institute. Retrieved March 13, 2023, from *https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/outreach-materials/visual-function-questionnaire-25*.

[405] Sivaprasad, S., Tschosik, E., Kapre, A., Varma, R., Bressler, N.M., Kimel, M., Dolan, C., & Silverman, D. (2018). Reliability and construct validity of the NEI VFQ–25 in a subset of patients with geographic atrophy from the Phase 2 mahalo study. American Journal of Ophthalmology, 190, 1–8. *https://doi.org/10.1016/j.ajo.2018.03.006*.

[406] Ibid.

[407] Ibid.

[408] Mangione CM, Phillips RS, Seddon JM, et al. Development of the 'Activities of Daily Vision Scale'. A measure of visual functional status. Med Care. 1992;30(12):1111–1126. *https://doi.org/10.1097/00005650-199212000-00004*.

[409] Hecht, I., Kanclerz, P., &; Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

specifications for ASCs to use for this measure, as both of these have even fewer survey questions to administer.

We also propose to allow ASCs to use the 14-item VF–14 and the 8-item VF–8R for administering and calculating this Cataracts Visual Function measure. Each can be administered in a shorter timeframe than the NEI VFQ–25 with high precision.[410] [411] Thus, the succinct formats of the VF–14 and VF–8R may ease ASCs' burden in administering the survey instruments, and potentially increase the rate of patient responses for this measure, as compared with other survey instrument options we considered. Therefore, we propose including the VF–14 and VF–8R for this measure's data collection specifications because we believe these survey instruments achieve results comparable with the longer NEI VFQ–25 and NEI VFQ–51 survey instruments with substantially fewer questions to administer.

Furthermore, we propose inclusion of the VF–14 because currently it is the most commonly used survey instrument and we believe it would be beneficial to allow the majority of physicians who have already been using the VF–14 to continue to have the option to do so.[412] The VF–14 is comprised of 14 items relating to daily living activities and function, such as reading, writing, seeing steps, stairs or curbs, and operating a motor vehicle.[413] Studies using this survey instrument generally report significant and clinically important improvement following cataract surgery.[414] The VF–14 additionally has achieved adequate reliability and validity, proving it to be a dependable survey instrument for cataract outcomes.[415] [416]

We propose the VF–8R, as it is the most concise of the three survey instruments, while still achieving adequate validity and reliability.[417] The VF–8R consists of questions related to reading, fine handwork, writing, playing board games, and watching television.[418] Given its conciseness compared to the majority of currently available survey instruments and its adequate psychometric properties, we believe that the VF–8R would be beneficial for measuring cataract surgery outcomes without prompting further patient survey fatigue.[419]

For these reasons, we believe that the NEI VFQ–25, VF–14, and VF–8R are the most appropriate survey instruments for ASCs to use to assess a patient's visual function pre- and post-cataract surgery for purposes of calculating and submitting data for the Cataracts Visual Function measure in the ASCQR Program.

To standardize survey instrument administration for the Cataracts Visual Function measure, we propose to limit the survey instruments that can be used to administer this measure, beginning with the voluntary CY 2024 reporting period, to these three survey instruments: (1) NEI VFQ–25; (2) VF–14; and (3) VF–8R. We believe the use of these three survey instruments to report data on the Cataracts Visual Function measure would allow for a more standardized approach to data collection. Having a limited number of allowable survey instruments would also address several commenters' request for additional guidance on survey instruments as well as improve measure reliability.

(3) Considerations for Data Collection Modes for the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Beginning With the Voluntary CY 2024 Reporting Period

As summarized in the CY 2023 OPPS/ASC final rule (87 FR 72118 through 72120), many commenters expressed concern about the high administrative burden of reporting the Cataracts Visual Function measure, as the measure uniquely requires coordination among clinicians of different specialties (that is, opticians and ophthalmologists). In an effort to decrease administrative burden surrounding in-office time constraints, we reiterate that, while we recommend the patient's physician or optometrist administer, collect, and report the survey results to the ASC, the survey instruments required for this measure can be administered by the ASC itself via phone, by the patient via regular or electronic mail, or during clinician follow-up.

Scientific literature supports the conclusion that self-administered survey instruments produce statistically reliable results.[420] [421] Furthermore, scientific literature indicates that regular mail and electronic mail surveys respectively, are preferred by varying subgroups of patients. The inclusion of both options ensures that patients will be able to respond to survey instruments in their preferred format.[422] [423] These findings support the inclusion of varying survey instrument-collection methods for patient and provider convenience.

We invite public comment on this proposal.

c. Proposed Modification of Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Denominator Change To Align With Current Clinical Guidelines Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

(1) Background

In 2019, colorectal cancer (CRC) accounted for the 4th highest rate of new cancer cases and 4th highest rate of cancer deaths in the United States.[424] The American Cancer Society (ACS) estimates that in 2023, 153,020 individuals will be newly diagnosed with CRC and 52,550 individuals will die from CRC in the United States.[425] The CDC advises, ''[c]olorectal cancer almost always develops from precancerous polyps (abnormal growths) in the colon or rectum. Screening tests can find precancerous

[410] Ibid.

[411] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[412] Hecht, I., Kanclerz, P., &; Tuuminen, R. (2022). Secondary outcomes of Lens and cataract surgery: More than just ''best-corrected visual acuity.'' Progress in Retinal and Eye Research, 101150. *https://doi.org/10.1016/j.preteyeres.2022.101150*.

[413] Ibid.

[414] Ibid.

[415] Ibid.

[416] Orizonartstudios. (2023). 2023 MIPS measure #303: Cataracts: Improvement in patient's visual function within 90 days following cataract surgery. MDinteractive. Retrieved March 13, 2023, from *https://mdinteractive.com/mips_quality_measure/2023-mips-quality-measure-303*.

[417] Ibid.

[418] Pre-Cataract Surgery—Visual Functioning Index (VF-8R) patient. (n.d.). *https://eyecaresite.com/wp-content/uploads/2020/02/Visual-Functioning-Index-Pre-Cat-SX.pdf*.

[419] Ibid.

[420] Bhandari, N. R., Kathe, N., Hayes, C., & Payakachat, N. (2018). Reliability and validity of SF–12V2 among adults with self-reported cancer. *Research in Social and Administrative Pharmacy*, 14(11), 1080–1084. *https://doi.org/10.1016/j.sapharm.2018.01.007*.

[421] Stolwijk, C., van Tubergen, A., Ramiro, S., Essers, I., Blaauw, M., van der Heijde, D., Landewe, R., van den Bosch, F., Dougados, M., & Boonen, A. (2014). Aspects of validity of the self-administered comorbidity questionnaire in patients with ankylosing spondylitis. *Rheumatology*, 53(6), 1054–1064. *https://doi.org/10.1093/rheumatology/ket354*.

[422] Kelfve, S., Kivi, M., Johansson, B., & Lindwall, M. (2020). Going web or staying paper? the use of web-surveys among older people. *https://doi.org/10.21203/rs.3.rs-21136/v4*.

[423] Meyer, V.M., Benjamens, S., Moumni, M.E., Lange, J.F., & Pol, R.A. (2020). Global overview of response rates in patient and health care professional surveys in surgery. *Annals of Surgery*, 275(1). *https://doi.org/10.1097/sla.0000000000004078*.

[424] Centers for Disease Control. (2022). Colorectal Cancer Statistics. Available at: *https://gis.cdc.gov/Cancer/USCS/#/AtAGlance/*.

[425] American Cancer Society. (2023). Cancer Facts & Figures 2023. Available at: *https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/2023-cancer-facts-figures.html*.

polyps, so that they can be removed before they turn into cancer. Screening tests can also find colorectal cancer early, when treatment works best. Regular screening, beginning at age 45, is the key to preventing colorectal cancer and finding it early.'' [426]

In May 2021, the United States Preventive Services Task Force (USPSTF) issued a revised Final Recommendation Statement on CRC Screening.[427] This replaced the prior USPSTF 2016 Final Recommendation Statement and included a number of updated policy recommendations based on new evidence and understandings of CRC and CRC screening. The USPSTF recommended that adults who do not have signs or symptoms of CRC and who are at average risk for CRC begin screening at age 45 instead of the previous recommendation of age 50.[428] In addition, multiple professional organizations, including the ACS, American Society of Colon and Rectal Surgeons, and the U.S. Multi-Society Task Force on Colorectal Cancer (which represents the American College of Gastroenterology, the American Gastroenterological Association, and the American Society for Gastrointestinal Endoscopy), recommend that people of average risk of CRC start regular screening at age 45.[429] [430] [431] Based on the recent changes in clinical guidelines to begin CRC screening at age 45 instead of age 50, we propose to modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients (the ''Colonoscopy Follow-Up Interval'') measure to follow these clinical guideline changes.

(2) Overview of Measure

We refer readers to the CMS Measures Inventory Tool and the ASCQR Specification Manual for more information on the Colonoscopy Follow-Up Interval measure, including background on the measure and a complete summary of measure specifications.[432] [433] Currently, the Colonoscopy Follow-Up Interval measure assesses the ''percentage of patients aged 50 years to 75 years receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report.'' [434] We propose to amend the measure's denominator language by replacing the phrase ''aged 50 years'' with the phrase ''aged 45 years.'' The measure denominator would be modified to ''all patients aged *45 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy'' from ''all patients aged *50 years to 75 years* receiving screening colonoscopy without biopsy or polypectomy.'' [435] We are not proposing any changes to the measure numerator, other measure specifications, exclusions, or data collection for the Colonoscopy Follow-Up Interval measure.

In the CY 2023 Physician Fee Schedule final rule (87 FR 69760 through 69767), we adopted the modified Colonoscopy Follow-Up Interval measure, which we propose here for the ASCQR Program, for the Merit-based Incentive Payment System (MIPS). We have considered the importance of aligning the minimum age requirement for CRC screening across quality reporting programs and clinical guidelines, and as a result, we propose to modify the Colonoscopy Follow-Up Interval measure denominator to ''all patients aged 45 to 75 years'' for the ASCQR Program. We propose the modification of the Colonoscopy Follow-Up Interval measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We invite public comment on this proposal.

5. Proposed Adoption of New Measures for the ASCQR Program Measure Set

Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, the provisions of section 1833(t)(17)(B) through (E) of the Act apply with respect to ASC services in a similar manner to the manner in which they apply to hospitals for the Hospital OQR Program. Section 1833(t)(17)(C)(i) of the Act requires the Secretary to develop measures appropriate for the measurement of the quality of care (including medication errors) furnished by hospitals in outpatient settings, that these measures reflect consensus among affected parties and, to the extent feasible and practicable, that these measures include measures set forth by one or more national consensus-based entities. We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

Section 1890A of the Act requires that we establish and follow a pre-rulemaking process for selecting quality and efficiency measures for our programs, including taking into consideration input from multi-stakeholder groups. As part of this pre-rulemaking process, the CBE, with which we contract under section 1890 of the Act, convened these groups under the Measure Applications Partnership (MAP). The MAP is a public-private partnership created for the primary purpose of providing input to HHS on the selection of measures as required by section 1890(b)(7)(B) of the Act, including measures for the ASCQR Program. We followed this pre-rulemaking process for both of the measures we propose for adoption for the ASCQR Program under this section of the proposed rule, as further detailed below.

In this proposed rule, we propose to: (1) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgica Procedures measure, with voluntary reporting in the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (2) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO-PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM), with

[426] Centers for Disease Control. (2022). What Should I Know About Screening?. Available at: *https://www.cdc.gov/cancer/colorectal/basic_info/screening/index.htm*.

[427] US Preventive Services Task Force. (2021). Screening for Colorectal Cancer. *JAMA*, 325(19), 1965–1977. *https://doi.org/10.1001/jama.2021.6238*.

[428] Ibid.

[429] Wolf A, Fontham ETH, Church TR, et al. (2018). Colorectal cancer screening for average-risk adults: 2018 guideline update from the American Cancer Society. *CA. Cancer J. Clin.*, 2018(68), 250–281. *https://doi.org/10.3322/caac.21457*.

[430] American Society of Colon & Rectal Surgeons. Colorectal Cancer Screening and Surveillance Recommendations of U.S. Multisociety Task Force. Available at: *https://fascrs.org/healthcare-providers/education/clinical-practice-guidelines/colorectal-cancer-screening-and-surveillance-recom*.

[431] Patel SG, May FP, Anderson JC, Burke CA, et al. (2022). Updates on Age to Start and Stop Colorectal Cancer Screening: Recommendations From the U.S. Multi-Society Task Force on Colorectal Cancer. *The American Journal of Gastroenterology*, 117(1), 57–69. *https://doi.org/10.14309/ajg.0000000000001548*.

[432] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1*.

[433] Qualitynet Home. (n.d.). Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals#tab6*.

[434] Centers for Medicare & Medicaid Services. (2023). Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=793&sectionNumber=1*.

[435] Ibid.

voluntary reporting beginning with the CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. In this section of the proposed rule, we provide additional information on these measure adoption proposals for the ASCQR Program.

a. Proposed Re-Adoption With Modification of the ASC Facility Volume Data on Selected ASC Surgical Procedures Measure Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

(1) Background

Hospital care has been gradually shifting from inpatient to outpatient settings.[436] Further, research indicates that volume of services performed in ASCs will continue to grow, with some estimates projecting a 25 percent increase in patients between 2019 and 2029.[437] In addition, as further discussed herein, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care, such as efficient team work and increased surgical experience.[438] In light of these trends in facility volume and more recent studies finding that volume is an indicator of quality, it is now especially important to track volume within ASCs, as it could provide valuable insight into the quality of ASCs' services for CMS and patients.

Although measuring the volume of procedures and other services has a long history as a quality metric, quality measurement efforts had moved away from collecting and analyzing data on volume because some considered volume simply a proxy for quality compared to directly measuring outcomes.[439] However, experts on quality and safety have recently suggested that, while volume may not alone indicate better outcomes, it is still an important component of quality.[440] [441] [442] Specifically, larger facility surgical procedure volume may be associated with better outcomes due to having characteristics that improve care.[443] For example, high-volume facilities may have teams that work more effectively together, or have superior systems or programs for identifying and responding to complications.[444] This association between volume and patient outcomes may be attributable to greater experience or surgical skill, greater comfort with and, hence, likelihood of application of standardized best practices, and increased experience in monitoring and management of surgical patients for the particular procedure.

The ASCQR Program does not currently include a quality measure for facility-level volume data, including surgical procedure volume data, but it did so previously. We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74507 through 74509) where we adopted the ASC Facility Volume Data on Selected ASC Surgical Procedures (ASC Procedure Volume) measure beginning with the CY 2015 payment determination. This structural measure of facility capacity collected surgical procedure volume data on seven categories of procedures frequently performed in the ASC setting: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, Respiratory, and Genitourinary.[445] We adopted the ASC Procedure Volume measure based on evidence that the volume of surgical procedures, particularly of high-risk surgical procedures, is related to better patient outcomes, including decreased mortality (76 FR 74507).[446] [447] We further stated our belief that publicly reporting volume data would provide patients with beneficial information to use when selecting a care provider (76 FR 74507).

In the CY 2018 OPPS/ASC final rule (82 FR 59449 through 59450), we stated our belief at that time that other measures in the ASCQR Program on specific procedure types, such as the Unplanned Anterior Vitrectomy measure, could provide patients with more valuable ASC quality of care information than the ASC Procedure Volume measure. Thus, we removed the ASC Procedure Volume measure beginning with the CY 2019 payment determination based on the availability of other measures that are ''more strongly associated with desired patient outcomes for the particular topic'' (currently Factor 6 in our regulation at § 416.320(c)(vi)) (82 FR 59449).

However, a commenter who opposed the removal of the ASC Procedure Volume measure at the time emphasized the measure data's usefulness for comparative research, outcomes research, immediate consumer value, and strategic planning (82 FR 59449). One commenter also expressed concern that non-availability of these data would interfere with the acceptance of ASC-based procedures, asserting that this measure helps to demonstrate the value of ASC-based procedures (82 FR 59449). These commenters further noted that the measure was not overly burdensome and, therefore, should not be removed (82 FR 59449). At the time, while we recognized the value of the measure and these concerns, we believed, overall, that the administrative burden and maintenance costs associated with this measure outweighed the benefits of keeping the measure in the ASCQR Program (82 FR 59449 through 59450).

In the CY 2023 OPPS/ASC final rule (87 FR 72127 through 72130), we stated that we have been considering re-adopting the ASC Procedure Volume measure for two reasons. First, since the removal of the ASC Procedure Volume measure, scientific literature has concluded that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where

[436] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Chapter 3. Available at: *https://www.medpac.gov/wp-content/uploads/2021/10/mar21_medpac_report_ch3_sec.pdf*.

[437] SG2 impact of Change Forecast predicts enormous disruption in health care provider landscape by 2029. Sg2. (2021). Retrieved March 28, 2023, from *https://www.sg2.com/media-center/press-releases/sg2-impact-forecast-predicts-disruption-health-care-provider-landscape-2029/*.

[438] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155*.

[439] Ibid.

[440] Ibid.

[441] Shang, M., Mori, M., Gan, G., Deng, Y., Brooks, C., Weininger, G., Sallam, A., Vallabhajosyula, P., & Geirsson, A. (2022). Widening volume and persistent outcome disparity in Valve Operations: New York Statewide Analysis, 2005–2016. The Journal of Thoracic and Cardiovascular Surgery, *164*(6). *https://doi.org/10.1016/j.jtcvs.2020.11.098*.

[442] Iwatsuki, M., Yamamoto, H., Miyata, H., Kakeji, Y., Yoshida, K., Konno, H., Seto, Y., & Baba, H. (2018). Effect of hospital and surgeon volume on postoperative outcomes after distal gastrectomy for gastric cancer based on data from 145,523 Japanese patients collected from a nationwide web-based data entry system. *Gastric Cancer, 22*(1), 190–201. *https://doi.org/10.1007/s10120-018-0883-1*.

[443] Jha AK. (2015) Back to the Future: Volume as a Quality Metric. JAMA Forum Archive. Published online June 10, 2015. *https://jamanetwork.com/channels/health-forum/fullarticle/2760155*.

[444] Ibid.

[445] ASC Specifications Manual version 5.1. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6*.

[446] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805*.

[447] Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. The New England Journal of Medicine, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

they receive care.[448] Further supporting this position that volume metrics are an indicator of quality, one study found an inverse volume-mortality relationship related to transfemoral transcatheter aortic-valve replacement (TAVR) procedures performed from 2015 through 2017.[449] Second, as discussed above, the recent shift of more surgical procedures being performed in outpatient settings has placed greater importance on tracking the volume of outpatient procedures in different settings, including ASCs. We believe that patients and their caregivers may benefit from the public reporting of facility-level volume measure data because the volume data illuminate which procedures are performed across ASCs, provide the ability to track volume changes by facility and procedure category, and can serve as an indicator for patients of which facilities are experienced with certain outpatient procedures. The ASC Procedure Volume measure was the only measure in the ASCQR Program measure set that captured facility-level volume within ASCs for both Medicare beneficiaries and non-Medicare patients. As a result of this measure's removal in the CY 2018 OPPS/ASC final rule, the ASCQR Program currently does not capture outpatient surgical procedure volume in ASCs.

In response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44750) regarding the potential inclusion of a volume measure in the ASCQR Program, a few commenters suggested that we can determine facility volumes for procedures performed using Medicare Fee-For-Service (FFS) claims (87 72129 through 72130). However, we note that the ASC Procedure Volume measure included the submission of both Medicare and non-Medicare volume data; thus, relying solely on the use of Medicare FFS claims data to simplify reporting would limit a future volume measure to only the Medicare program payer, leading to an incomplete representation of ASCs' procedural volume.[450]

Additionally, in response to our request for comment in the CY 2023 OPPS/ASC proposed rule (87 FR 44748 through 44750), a few commenters stated that they believe there is a lack of evidence proving the correlation between volume and quality (87 FR 72129 through 72130). However, many studies in recent years have shown that volume does serve as an indicator of quality of care.[451] [452] For example, studies published since the CY 2018 OPPS/ASC final rule found that patients at high volume hospitals for a specific procedure had lower rates of surgical site infections, complications, and mortality compared to patients at low-volume hospitals.[453] [454] We reiterate our belief, grounded in this published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and assist consumers in making informed decisions about where they receive care.[455] [456]

(2) Overview of Measure

(a) Data Collection, Submission, Reporting, and Measure Specifications

The proposed ASC Procedure Volume measure collects data regarding the aggregate count of selected surgical procedures. Most ASC procedures fall into one of eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[457] For this proposed measure, data surrounding the top five most frequently performed procedures among ASCs in each category will be collected and publicly displayed. The top five procedures in each category would be assessed and updated annually as needed to ensure data collection of most accurate and frequently performed procedures.[458]

We propose that ASCs would submit aggregate-level data through the CMS web-based tool (currently the Hospital Quality Reporting (HQR) system), consistent with what was required during the measure's initial adoption (76 FR 74508). Data received through the HQR system would then be publicly displayed on the *data.cms.gov* website or another CMS website. We refer readers to § 416.315 for our codified policies regarding public reporting of data under the ASCQR Program.

We propose to re-adopt the ASC Procedure Volume measure with modification, with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. At the time of this measure's initial adoption in the CY 2012 OPPS/ASC final rule (76 FR 74509), we finalized that ASCs would report all-patient volume data with respect to six categories: Gastrointestinal, Eye, Nervous System, Musculoskeletal, Skin, and Genitourinary. The first modification of this previously adopted measure that we propose is that the ASC Procedure Volume measure data collection will cover eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin. Furthermore, in response to commenter concerns regarding potential difficulty detecting procedural volume differention among these broad based categories (76 FR 74508), the second modification to this measure that we propose is that instead of collecting and publicly displaying data surrounding these eight broad categories, we would more granularly collect and publicly display data reported for the top five most frequently performed procedures among ASCs within each category will be collected. We refer readers to the Center for Medicare and Medicaid Services Inventory Tool for more information on this measure: *https://cmit.cms.gov/cmit/#/*.

[448] Ogola GO, Crandall ML, Richter KM, & Shafi S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985*.

[449] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

[450] The specifications for the removed ASC Procedure Volume measure are available in the ASC Specifications Manual version 5.1 available at *https://qualitynet.cms.gov/asc/specifications-manuals#tab6*.

[451] Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; & Shafi, Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018—Volume 85—Issue 3—p 560–565 *https://doi.org/10.1097/TA.0000000000001985*.

[452] Vemulapalli, S., Carroll, J., & Mack, M. et al. (2019) Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine, 380*(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

[453] Mufarrih, S.H., Ghani, M.O.A., Martins, R.S. et al. (2019) Effect of hospital volume on outcomes of total hip arthroplasty: a systematic review and metaanalysis. J Orthop Surg Res 14, 468. *https://doi.org/10.1186/s13018-019-1531-0*.

[454] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805*.

[455] Ogola GO, Crandall ML, Richter KM, Shafi, S. (2018). High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. *Journal of Trauma and Acute Care Surgery*, 85(3), 560–565. *https://doi.org/10.1097/TA.0000000000001985*.

[456] Vemulapalli S, Carroll J, Mack M, et al. (2019). Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement. *The New England Journal of Medicine*, 380(26), 2541–2550. *https://doi.org/10.1056/NEJMsa1901109*.

[457] ASC Specifications Manual version 1.0b. Available at: *https://qualitynet.cms.gov/asc/specifications-manuals#tab6*.

[458] Data source: Clinical Data Warehouse; CMS ASC Part B claims for encounters January 1, 2022–December 31, 2022.

We also propose that ASCs submit these data to CMS during the time period of January 1 through May 15 in the year prior to the affected payment determination year. For example, for the CY 2028 payment determination, the data submission period would be January 1, 2027 to May 15, 2027, covering the performance period of January 1, 2026 to December 31, 2026. We refer readers to section XV.D.1.c of this proposed rule for a more detailed discussion of the requirements for data submitted via a CMS online web-based tool. We previously codified our existing policies regarding data collection and submission under the ASCQR Program at § 416.310.

(b) Review by the Measure Applications Partnership (MAP)

The MAP conditionally supported the ASC Procedure Volume measure for rulemaking, pending testing indicating that the measure is reliable and valid, and endorsement by a CBE.[459] Additionally, the MAP noted that electronic reporting of procedure volumes based on code lists should not be overly burdensome to ASCs, and the public reporting of specific procedure volumes may be useful to patients.

The MAP members expressed differing views on the value of volume data to patients. Specifically, the MAP members representing patients stated the measure would be useful to patients as they decide where to seek care, as one data point along with others (for example, advice from providers). However, other MAP members expressed concern about the value of volume data for informing patient decisions without other context and encouraged the use of outcome measures instead.[460]

As discussed above, we reiterate that various studies have found that there is a well-established positive correlation between the volume of procedures performed at a facility and the clinical outcomes resulting from that procedure. For instance, a recent systematic review highlighted by the MAP found a significant volume-outcome relationship in the vast majority (87 percent) of the 403 studies analyzed.[461] The MAP noted a similar review focused on outpatient surgeries that similarly found a significant volume-outcome relationship across eight studies.[462]

The MAP stated that this measure addresses a national trend in which surgeries are moving from hospital inpatient settings to ASCs, and that public reporting of this measure could help CMS and the public better understand differences in the quality of care provided at facilities.[463] The MAP reported that ASC Procedure Volume measure data from 2015 and 2016 demonstrates variation in performance in the number of procedures performed by facilities in the 25th and 75th percentiles across the condition categories.[464] These findings support our belief, grounded in additional published scientific literature, that volume metrics serve as an indicator of which facilities are experienced with certain outpatient procedures and can assist consumers in making informed decisions about where they receive care.[465] [466]

In addition, the MAP noted the concurrent submission of MUC (Measures Under Consideration) 2022–030: Hospital Outpatient Department Volume Data on Selected Outpatient Surgical Procedures for inclusion in the Hospital Outpatient Quality Reporting (OQR) Program.[467] The MAP highlighted that the specifications of the volume measure proposed for the Hospital OQR Program are aligned with the volume measure we propose for the ASCQR Program and, therefore, would facilitate comparisons of equivalent procedure volumes across ASCs and hospital outpatient departments (HOPDs), one of the key goals of the Hospital OQR and ASCQR Programs.

(c) Measure Endorsement

As discussed in the previous subsection of the proposed rule, the MAP reviewed and conditionally supported the ASC Procedure Volume measure pending testing indicating the measure is reliable and valid, and endorsement by a national consensus-based entity as the measure was not submitted for endorsement. We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from endorsement by a national consensus-based entity, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment.

We considered the MAP's recommendation and propose to adopt the measure because we did not find any other measures of procedure volume and this measure was previously used in the ASCQR Program, with supporters of its use. Given the support from the MAP and feedback from public comment, as well as the increasing shift from inpatient to outpatient surgical procedures and evidence that volume metrics can promote higher quality healthcare for patients, we propose the readoption of this measure, with two modifications, in the ASCQR Program pending endorsement from a national consensus-based entity.

We invite public comment on this proposal.

b. Proposed Adoption of the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) Beginning With Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

(1) Background

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we adopted the THA/TKA PRO–PM in the Hospital Inpatient Quality Reporting (IQR) Program beginning with voluntary reporting periods in FY 2025 and FY 2026, followed by mandatory reporting for eligible elective procedures

[459] Pre-rulemaking MUC lists and map reports. Pre-Rulemaking MUC Lists and MAP Reports | The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[460] Ibid.

[461] Levaillant, M., Marcilly, R., Levaillant, L., Michel, P., Hamel-Broza, J.F., Vallet, B., & Lamer, A. (2021). Assessing the hospital volume-outcome relationship in surgery: A scoping review. *BMC Medical Research Methodology, 21*(1). *https://doi.org/10.1186/s12874-021-01396-6*.

[462] Stanak, M., & Strohmaier, C. (2020). Minimum volume standards in day surgery: A systematic review. *BMC Health Services Research, 20*(1). *https://doi.org/10.1186/s12913-020-05724-2*.

[463] Medicare Payment Advisory Commission. March 2021 Report to the Congress: Medicare Payment Policy. Available at: *https://www.medpac.gov/document/march-2021-report-to-the-congress-medicare-payment-policy/*.

[464] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[465] Ogola, Gerald O. Ph.D., MPH; Crandall, Marie L. MD, MPH; Richter, Kathleen M. MS, MBA, MFA; Shafi, & Shahid MD, MPH. (2018) High-volume hospitals are associated with lower mortality among high-risk emergency general surgery patients. Journal of Trauma and Acute Care Surgery: September 2018—Volume 85—Issue 3—p 560–565. *https://doi.org/10.1097/TA.0000000000001985*.

[466] Saito, Y., Tateishi, K., Kanda, M., Shiko, Y., Kawasaki, Y., Kobayashi, Y., & Inoue, T. (2022). Volume-outcome relationships for percutaneous coronary intervention in acute myocardial infarction. *Journal of the American Heart Association, 11*(6). *https://doi.org/10.1161/jaha.121.023805*.

[467] Pre-rulemaking MUC lists and map reports. The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

occurring July 1, 2024 through June 30, 2025 for the FY 2028 payment determination. In this proposed rule, we propose the adoption of the THA/TKA PRO–PM into the ASCQR Program using the same specifications as finalized for the hospital-level measure adopted into the Hospital IQR Program (87 FR 49246 through 49257) with modifications to include procedures performed in the ASC setting.

Approximately six million adults aged 65 or older suffer from osteoarthritis in the United States.[468] In 2013, there were approximately 568,000 hospitalizations billed to Medicare for osteoarthritis.[469] Hip and knee osteoarthritis is one of the leading causes of disability among non-institutionalized adults,[470 471] and roughly 80 percent of patients with osteoarthritis have some limitation in mobility.[472 473] Elective THA and TKA are most commonly performed for degenerative joint disease or osteoarthritis, which affects more than 30 million Americans.[474] THA and TKA offer the potential for significant improvement in quality of life by decreasing pain and improving function in a majority of patients, without resulting in a high risk of complications or death.[475 476 477] However, not all patients experience benefit from these procedures.[478] Many patients note that their pre-operative expectations for functional improvement have not been met.[479 480 481 482] In addition, clinical practice variation has been well documented in the United States,[483 484 485 486 487] readmission and complication rates vary across hospitals,[488 489] and international experience documents wide hospital-level variation in patient-reported outcome measure results following THA and TKA.[490]

Due to the absence of recently conducted, large scale and uniformly collected patient-reported outcome (PRO) data available from patients undergoing elective primary THA/TKA, we established an incentivized, voluntary PRO data collection opportunity within the Comprehensive Care for Joint Replacement (CJR) model to support measure development.[491] Elective THA/TKAs are important, effective procedures performed on a broad population, and the patient outcomes for these procedures (such as pain, mobility, and quality of life) can be measured in a scientifically sound way,[492 493] are influenced by a range of improvements in care,[494] and demonstrate hospital-level variation even after patient case mix adjustment.[495 496] Further, THA/TKA procedures are specifically intended to improve function and reduce pain,

[468] Arthritis Foundation. (2018). Arthritis By the Numbers Book of Trusted Facts and Figures. Accessed March 8, 2019. Available at: *https://www.arthritis.org/getmedia/e1256607-fa87-4593-aa8a-8db4f291072a/2019-abtn-final-march-2019.pdf*.

[469] Torio CM, & Moore BJ. (2016). National inpatient hospital costs: the most expensive conditions by payer, 2013. HCUP statistical brief #204. Healthcare Cost and Utilization Project (HCUP) Statistical Briefs. Rockville, MD, Agency for Healthcare Research and Quality. Available at: *https://www.ncbi.nlm.nih.gov/books/NBK368492/*.

[470] Guccione AA, Felson DT, Anderson JJ, et al. (1994). The effects of specific medical conditions on the functional limitations of elders in the Framingham Study. *American journal of public health*, 84(3), 351–358. *https://www.doi.org/10.2105/AJPH.84.3.351*.

[471] Barbour KE, Helmick CG, Boring M, & Brady TJ. (2017). Vital Signs: Prevalence of Doctor-Diagnosed Arthritis and Arthritis-Attributable Activity Limitation—United States, 2013–2015. MMWR Morbidity and mortality weekly report, 66(9), 246–253. *https://www.doi.org/10.15585/mmwr.mm6609e1*.

[472] Michaud CM, McKenna MT, Begg S, et al. (2006). The burden of disease and injury in the United States 1996. *Population health metrics*, 4, 11. *https://doi.org/10.1186/1478-7954-4-11*.

[473] Theis KA, Murphy LB, Baker NA, & Hootman JM. (2019). When you can't walk a mile: Walking limitation prevalence and associations among middle-aged and older US adults with Arthritis: A cross-sectional, population-based study. *ACR Open Rheumatol*, 1(6), 350–358. *https://www.doi.org/10.1002/acr2.11046*.

[474] Centers for Disease Control and Prevention. Osteoarthritis (OA). Accessed March 8, 2019. Available at: *https://www.cdc.gov/arthritis/basics/osteoarthritis.htm*.

[475] Rissanen P, Aro S, Slatis P, et al. (1995). Health and quality of life before and after hip or knee arthroplasty. *The Journal of arthroplasty*, 10(2), 169–175. *https://www.doi.org/10.1016/s0883-5403(05)80123-8*.

[476] Ritter MA, Albohm MJ, Keating EM, et al. (1995). Comparative outcomes of total joint arthroplasty. *The Journal of arthroplasty*, 10(6), 737–741. *https://doi.org/10.1016/s0883-5403(05)80068-3*.

[477] Sayah SM, Karunaratne S, Beckenkamp PR, et al. (2021). Clinical Course of Pain and Function Following Total Knee Arthroplasty: A Systematic Review and Meta-Regression. *J Arthroplasty*, 36(12), 3993–4002.e37. *https://www.doi.org/10.1016/j.arth.2021.06.019*.

[478] National Joint Registry. National Joint Registry for England and Wales 9th Annual Report 2012. Available at: *https://www.hqip.org.uk/wp-content/uploads/2018/02/national-joint-registry-9th-annual-report-2012.pdf*.

[479] Suda AJ, Seeger JB, Bitsch RG, et al. (2010). Are patients' expectations of hip and knee arthroplasty fulfilled? A prospective study of 130 patients. *Orthopedics*, 33(2), 76–80. *https://www.doi.org/10.3928/01477447-20100104-07*.

[480] Ghomrawi HM, Franco Ferrando N, Mandl LA, et al. (2011). How Often are Patient and Surgeon Recovery Expectations for Total Joint Arthroplasty Aligned? Results of a Pilot Study. *HSS journal: The musculoskeletal journal of Hospital for Special Surgery*, 7(3), 229–234. *https://www.doi.org/10.1007/s11420-011-9203-6*.

[481] Harris IA, Harris AM, Naylor JM, et al. (2013). Discordance between patient and surgeon satisfaction after total joint arthroplasty. *The Journal of arthroplasty*, 28(5), 722–727. *https://www.doi.org/10.1016/j.arth.2012.07.044*.

[482] Jourdan C, Poiraudeau S, Descamps S, et al. (2012). Comparison of patient and surgeon expectations of total hip arthroplasty. *PloS one*, 7(1), e30195. *https://www.doi.org/10.1371/journal.pone.0030195*.

[483] Roos EM. (2003). Effectiveness and practice variation of rehabilitation after joint replacement. *Current opinion in rheumatology*, 15(2),160–162. *https://doi.org/10.1097/00002281-200303000-00014*.

[484] Anderson FA, Huang W, Friedman RJ, et al. (2012). Prevention of venous thromboembolism after hip or knee arthroplasty: findings from a 2008 survey of US orthopedic surgeons. *The Journal of arthroplasty*, 27(5), 659–666 e655. *https://doi.org/10.1016/j.arth.2011.09.001*.

[485] American Academy of Orthopaedic Surgeons. (2011). Preventing Venous Thromboembolic Disease in Patients Undergoing Elective Hip and Knee Arthroplasty: Evidence-Based Guideline and Evidence Report. *https://www.aaos.org/globalassets/quality-and-practice-resources/vte/vte_full_guideline_10.31.16.pdf*.

[486] Pincus D, et al. (2020). Association Between Surgical Approach and Major Surgical Complications in Patients Undergoing Total Hip Arthroplasty. *JAMA*, 323(11), 1070–1076. *https://doi.org/10.1001/jama.2020.0785*.

[487] Siebens HC, Sharkey P, Aronow HU, et al. (2016). Variation in Rehabilitation Treatment Patterns for Hip Fracture Treated With Arthroplasty. *PM&R*, 8(3), 191–207. *https://doi.org/10.1016/j.pmrj.2015.07.005*.

[488] Suter LG, Grady JN, Lin Z, et al. 2013 Measure Updates and Specifications: Elective Primary Total Hip Arthroplasty (THA) And/OR Total Knee Arthroplasty (TKA) All-Cause Unplanned 30-Day Risk-Standardized Readmission Measure (Version 2.0). March 2013. Available at: *http://qualitynet.org/*.

[489] Suter LG, Parzynski CS, Grady JN, et al. 2013 Measures Update and Specifications: Elective Primary Total Hip Arthroplasty (THA) AND/OR Total Knee Arthroplasty (TKA) Risk-Standardized Complication Measure (Version 2.0). March 2013. Available at: *http://qualitynet.org/*.

[490] Rolfson O. (2010). Patient-reported Outcome Measures and Health-economic Aspects of Total Hip Arthroplasty: A study of the Swedish Hip Arthroplasty Register. Accessed July 20, 2013. Available at: *https://gupea.ub.gu.se/bitstream/handle/2077/23722/gupea_2077_23722_1.pdf?sequence=1*.

[491] Centers for Medicare & Medicaid Services. Comprehensive Care for Joint Replacement Model. Available at: *https://innovation.cms.gov/innovation-models/cjr*.

[492] Liebs TR, Herzberg W, Ruther W, et al. (2016). Quality-adjusted life years gained by hip and knee replacement surgery and its aftercare. *Archives of physical medicine and rehabilitation*, 97(5), 691–700. *https://doi.org/10.1016/j.apmr.2015.12.021*.

[493] White D, & Master H. (2016). Patient Reported Measures of Physical Function in Knee Osteoarthritis. *Rheum Dis Clin North Am*, 42(2), 239–252. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4853650/*.

[494] Kim K, Anoushiravani A, Chen K, et al. (2019). Perioperative Orthopedic Surgical Home: Optimizing Total Joint Arthroplasty Candidates and Preventing Readmission. *Journal of Arthroplasty*, 34(7), S91–S96. *https://doi.org/10.1016/j.arth.2019.01.020*.

[495] Bozic KJ, Grosso LM, Lin Z, et al. (2014). Variation in hospital-level risk-standardized complication rates following elective primary total hip and knee arthroplasty. *The Journal of Bone and Joint Surgery*, 96(8), 640–647. *https://www.doi.org/10.2106/JBJS.L.01639*.

[496] Makela KT, Peltola M, Sund R, et al. (2011). Regional and hospital variance in performance of total hip and knee replacements: A national population-based study. *Annals of medicine*, 43(sup1), S31–S38. *https://doi.org/10.3109/07853890.2011.586362*.

making PROs a meaningful outcome metric to assess.[497]

In the CY 2021 OPPS/ASC final rule (85 FR 86146), we announced that THA and TKA procedures were removed from the Inpatient Only Procedures (IPO) list and added to the ASC covered procedures list (CPL). As a result, the volume of THA and TKA procedures for Medicare beneficiaries aged 65 years and older have been increasing in outpatient settings, including ASCs.

We analyzed Part B Medicare FFS claims data for the number of ASC facility claims with THA/TKA procedures during CYs 2020, 2021, and 2022 (Table 74 below). Though we acknowledge that currently the total number of ASCs performing these procedures, and the number of procedures being performed in ASCs, is relatively low and there is wide variation in number of procedures performed in those ASCs, the number of procedures performed in the ASC setting has steadily grown.

BILLING CODE 4120–01–P

TABLE 74: Distribution of Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) claims per ASC CY 2020-2021

CY	CPT	CPT Description	# ASCs with THA/TKA Claims	Median # of Claims	Mean # of Claims	Std Dev	Min	Max
2020	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	8	1	1.38	0.74	1	3
2020	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	568	8	19.20	32.87	1	296
2020	27130, 27447	All THA/TKA	569	8	19.18	32.90	1	296
2021	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	550	7	16.80	28.94	1	351
2021	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	749	12	28.20	46.57	1	509
2021	27130, 27447	All THA/TKA	782	16	38.83	69.01	1	860
2022	27130	ARTHRP ACETBLR/PROX FEM PROSTC AGRFT/ALGRFT	646	10	21.45	33.80	1	354
2022	27447	ARTHRP KNE CONDYLE&PLAT U MEDIAL&LAT COMPARTMENTS	854	16	33.78	53.85	1	594
2022	27130, 27447	All THA/TKA	881	22	48.47	80.81	1	948

Data source: CMS analysis, Medicare Part B claims January 1, 2020 - December 31, 2022 with a CPT code of 27130 or 27447

BILLING CODE 4120–01–C

In the CY 2022 OPPS/ASC proposed rule (86 FR 42251 through 42252), we requested comment on the potential future adoption of the THA/TKA PRO–PM into the ASCQR Program. We refer readers to the CY 2022 OPPS/ASC final

[497] Liebs T, Herzberg W, Gluth J, et al. (2013). Using the patient's perspective to develop function short forms specific to total hip and knee replacement based on WOMAC function items. *The Bone & Joint Journal*, 95(B), 239–243. *https://www.doi.org/10.1302/0301-620X.95B2.28383*.

rule (86 FR 63896 through 63898) for a complete summary of feedback from interested parties.

Many commenters supported inclusion of the THA/TKA PRO–PM to the ASCQR Program as procedures move from inpatient to outpatient settings. Commenters noted it was important to monitor quality outcomes and publicly report results. Additionally, commenters stated that the measure is aligned with patient values, being presented in a manner that is easy to understand.

Other commenters did not support expansion of the measure to the ASCQR Program, and expressed concern with data collection burden, patient survey fatigue, and reporting thresholds. While we recognize that patient-reported outcome (PRO) based performance measures require providers to integrate data collection into clinical workflows, this integration provides opportunity for PROs to inform clinical decision making and benefits patients by engaging them in discussions about potential outcomes. Furthermore, we do not expect this measure to contribute to survey fatigue as the PRO instruments used to calculate pre- and post-operative scores for this THA/TKA PRO–PM were carefully selected, with extensive interested party input, to be low burden for patients.[498] [499]

We propose to adopt the THA/TKA PRO–PM into the ASCQR Program beginning with two voluntary reporting periods, followed by mandatory reporting. The first voluntary reporting period would begin with the CY 2025 reporting period for eligible elective outpatient procedures between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with the CY 2026 reporting period for eligible outpatient procedures between January 1, 2026 through December 31, 2026. Mandatory reporting would begin with the CY 2027 reporting period/CY 2030 payment determination for eligible elective outpatient procedures occurring January 1, 2027 through December 31, 2027, impacting the CY 2030 payment determination and subsequent years. Because this proposed measure requires collection of data during the 3-month pre-operative period and the greater than 1-year post-operative period, there is a delay between when the elective THA/TKA procedures actually occur, when the results would be reported under the ASCQR Program, and when payment determinations occur. Therefore, we propose a 3-year gap between the reporting period and the payment determination year (for example, CY 2027 reporting period for the CY 2030 payment determination) for the ASCQR Program. We refer readers to section XV.B.5.b.(2)(a) of this proposed rule for more information on the reporting requirements.

(2) Overview of Measure

(a) Data Collection, Submission, Reporting and Measure Specifications

This measure reports the facility-level risk-standardized improvement rate (RSIR) in PROs following elective primary THA/TKA for Medicare FFS beneficiaries aged 65 years and older who were enrolled in Medicare FFS Part A and B for the 12 months prior to the date of the procedure and in Medicare FFS Part A and B during the procedure. The measure includes only elective primary outpatient THA/TKA procedures (patients with fractures and revisions are not included) performed at ASCs and does not include any inpatient procedures. The measure excludes patients with staged procedures (multiple elective primary THA or TKA procedures performed on the same patient during distinct encounters) that occur during the measurement period and excludes discontinued procedures (that is, procedures that were started but not completed).[500]

Substantial clinical improvement is measured by achieving a pre-defined improvement in score on one of the two validated joint-specific PRO instruments measuring hip or knee pain and functioning: (1) The Hip Dysfunction and Osteoarthritis Outcome Score for Joint Replacement (HOOS, JR) for completion by THA recipients; or (2) the Knee injury and Osteoarthritis Outcome Score for Joint Replacement (KOOS, JR) for completion by TKA recipients. Improvement is measured from the pre-operative assessment (data collected 90 to 0 days before surgery) to the post-operative assessment (data collected 300 to 425 days following surgery). Improvement scores are risk-adjusted to account for differences in patient case-mix. The measure, as proposed, accounts for potential non-response bias in measure scores through inverse probability weighting based on likelihood of response.

We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257) for more information on the development of the hospital-level THA/TKA PRO–PM, including background on the measure and a complete summary of measure specifications, data sources, and measure calculation.

For additional details regarding the measure specifications, we also refer readers to the Hip and Knee Arthroplasty Patient-Reported Outcomes file, available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

(i) Data Sources

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) PRO data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. As described in section XV.B.5.b.(1) of this proposed rule, the measure uses PRO data directly reported by the patient regarding their health, quality of life, or functional status associated with their health care or treatment. This patient reported-data are collected by facilities pre-operatively and post-operatively, and limited patient-level risk factor data are collected with PRO data and identified in claims as detailed in this section of the proposed rule.[501] The measure includes PRO data collected with the two joint-specific PRO instruments described in this section of the proposed rule—the HOOS, JR for completion by THA recipients and the KOOS, JR for completion by TKA recipients—from which scores are used to assess substantial clinical improvement. For risk-adjustment by pre-operative mental health score, ASCs would submit one of two additional PRO instruments, all the items in either the: (1) the Patient-Reported Outcomes Measurement Information System (PROMIS)-Global Mental Health subscale; or (2) the Veterans RAND 12-Item Health Survey (VR–12) Mental Health subscale. The risk model also includes a one-question patient-reported assessment of health literacy—the Single Item Literacy Screener questionnaire.

[498] *Pre-rulemaking MUC lists and map reports.* The Measures Management System. (n.d.). Retrieved March 13, 2023, from *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[499] Centers for Medicare and Medicaid Services Measures Inventory Tool. (n.d.). Retrieved March 28, 2023, from *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11547&sectionNumber=1.*

[500] U.S. Department of Health and Human Services. (2021). Hospital Outpatient Prospective Payment System (OPPS): Use of Modifiers –52, –73, and –74 for Reduced or Discontinued Services. Available at: *https://www.hhs.gov/guidance/document/hospital-outpatient-prospective-payment-system-opps-use-modifiers-52-73-and-74-reduced-or.*

[501] Higgins JP, Thomas J, Chandler J, et al. (2019). Cochrane handbook for systematic reviews of interventions. John Wiley & Sons. *https://doi.org/10.1002/9781119536604.*

Furthermore, the following data would be collected for identification of the measure cohort, for risk-adjustment purposes, and for the statistical approach to potential non-response bias. ASC facility claims data would be used to identify eligible elective primary outpatient THA/TKA procedures for the measure cohort to which submitted PRO data can be matched, and to identify additional variables for risk-adjustment and in the statistical approach to account for response bias, including patient demographics and clinical comorbidities up to 12 months prior to surgery. The Medicare Enrollment Database (EDB) identifies Medicare FFS enrollment and patient-identified race, and the Master Beneficiary Summary File allows for determination of Medicare and Medicaid dual eligibility enrollment status. Demographic information from the U.S. Census Bureau's American Community Survey allows for derivation of the Agency for Healthcare Research and Quality (AHRQ) Socioeconomic Status (SES) Index score. Race, dual eligibility, and AHRQ SES Index score are used in the statistical approach to account for potential non-response bias in the outcome calculation. We refer readers to section XV.B.5.b.(2)(iii) of this proposed rule for further details regarding the variables required for data collection and submission.

(ii) Measure Calculation

The ASC facility-level THA/TKA PRO–PM result is calculated by aggregating all patient-level results across the facility. This measure would be calculated and presented as a RSIR, producing a performance measure per facility which accounts for patient case-mix, addresses potential non-response bias, and represents a measure of quality of care following elective primary outpatient THA/TKA. Response rates for PRO data would be calculated as the percentage of elective primary ASC THA or TKA procedures for which complete and matched pre-operative and post-operative PRO data have been submitted divided by the total number of eligible THA or TKA procedures performed at each facility.

(iii) Data Submission and Reporting

In response to feedback received from interested parties in the request for comments (RFCs) on this measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and the CY 2022 OPPS/ASC proposed rule (86 FR 42251 through 42252) and adoption of the measure in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we propose to adopt the THA/TKA PRO–PM in the ASCQR Program utilizing flexible data submission approaches.

ASCs would submit the following variables collected pre-operatively between 90 and zero days prior to the THA/TKA procedure for each patient: Medicare provider number; Medicare health insurance claim (HIC) number/Medicare beneficiary identifier (MBI); date of birth; date of procedure; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; patient-reported outcome measure version; PROMIS Global (mental health subscale items) or VR–12 (mental health subscale items); HOOS, JR (for THA patients); KOOS, JR (for TKA patients); Single-Item Health Literacy Screening (SILS2) questionnaire; BMI or weight (kg)/height (cm); chronic (≥90 day) narcotic use; total painful joint count (patient reported in non-operative lower extremity joint); and quantified spinal pain (patient-reported back pain, Oswestry index question[502] [503]).

ASCs would submit the following variables collected post-operatively between 300 and 425 days following the THA/TKA procedure for each patient: Medicare provider number; Medicare HIC number/MBI; date of birth; procedure date; date of PRO data collection; procedure type; mode of collection; person completing the survey; facility admission date; KOOS, JR (TKA patients); and HOOS, JR (THA patients). The data submission period for the THA/TKA PRO–PM would also serve as the review and correction period. Data would not be able to be corrected following the submission deadline.

We propose a phased implementation approach for adoption of this measure to the ASCQR Program, with voluntary reporting periods in CYs 2025 and CY 2026 followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination in the ASCQR Program. Voluntary reporting prior to mandatory reporting would allow time for facilities to incorporate the THA/TKA PRO–PM data collection into their clinical workflows and is responsive to interested parties' comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45408 through 45414) and FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257). Given the numbers of ASCs, varied number of procedures being performed, and the extended follow-up periods, we considered extending the length of voluntary reporting.

Following the two voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO–PM would begin with the CY 2027 reporting period/CY 2030 payment determination. For each voluntary and subsequent mandatory reporting period, we would collect data on the THA/TKA PRO–PM in accordance with Health Insurance Portability and Accountability Act of 1996 (HIPAA), Privacy and Security Rules (45 CFR parts 160 and 164, subparts A, C, and E), and other applicable law.

(b) Review by Measure Applications Partnership (MAP)

We included the THA/TKA PRO–PM measure for the ASCQR Program in the publicly available ''2022 Measures Under Consideration List.'' (MUC2022–026).[504] The MAP Coordinating Committee supported the measure, as referenced in the MAP's 2022–2023 Final Recommendations report to HHS and CMS.[505]

The MAP members noted that, while a similar version of this measure has been adopted for use in the Hospital IQR program, a measure that assesses PROs among THA/TKA patients in ASCs for the ASCQR Program does not currently exist. The MAP highlighted the key strategy for the ASCQR Program is to ensure that procedures done in any type of facility have equivalent quality. As such, the MAP members agree that quality measures regarding procedures in hospital settings should be incorporated into the ASCQR Program, to the extent feasible and appropriate, so that consumers can compare quality of a specific procedure across different facility types, including ASCs.[506]

In addition, the MAP members stated that the goal of the THA/TKA PRO–PM is to capture the full spectrum of care to incentivize collaboration and shared responsibility for improving patient health and reducing the burden of their disease. They agreed that this measure aligns with the goal of patient-centered approaches to health care quality improvement and addresses the high priority areas of patient and family

[502] Fairbank JC, & Pynsent PB. (2000). The Oswestry Disability Index. Spine. 25(22), 2940–52 *https://journals.lww.com/spinejournal/Abstract/2000/11150/The_Oswestry_Disability_Index.17.aspx.*

[503] The Oswestry Disability Index is in the public domain and available for all hospitals to use.

[504] 2022 Measures Under Consideration List. Available at *https://mmshub.cms.gov/sites/default/files/2022-MUC-List.xlsx.*

[505] MAP MUC Preliminary Recommendations 2022–2023. Available at *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[506] Ibid.

engagement, communication, and care coordination for the ASCQR Program.[507]

(c) Measure Endorsement

The CBE endorsed the hospital-level version of the THA/TKA PRO–PM (CBE #3559) in November 2020.[508] We note that the ASCQR Program version of the THA/TKA PRO–PM currently uses the same specifications as the CBE endorsed hospital-level THA/TKA PRO–PM with modifications that allow for the capture of procedures performed in for the ASC setting. We intend to seek CBE endorsement for the ASCQR Program's version of the THA/TKA PRO–PM in a future endorsement cycle.

We have noted in previous rulemaking (76 FR 74494) the requirement that measures reflect consensus among affected parties can be achieved in other ways aside from CBE endorsement, including through the measure development process, through broad acceptance, use of the measure(s), and through public comment. We propose this measure without CBE-endorsement based upon strong MAP and public support combined with the importance of the measure for Medicare beneficiaries. In addition, there are two existing, CBE-endorsed versions of this measure, one at the clinician-group level (CBE #3639) and one for the hospital level (CBE #3559). We expect that the measure will perform similarly in the ASC setting, and we intend on submitting the measure for CBE endorsement following data collection during voluntary reporting.

We refer readers to section XV.D.1.d of this proposed rule for a discussion on the THA/TKA PRO–PM form, manner, and timing submission requirements.

We invite public comment on this proposal.

6. ASCQR Program Quality Measure Set

a. Summary of Previously Finalized and Newly Proposed ASCQR Program Quality Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2023 OPPS/ASC final rule (87 FR 72120 through 72121) for the previously finalized ASCQR Program measure set for the CY 2024 reporting period/CY 2026 payment determination.

Table 75 below summarizes the previously finalized and newly proposed ASCQR Program measures for the CY 2024 reporting period/CY 2026 payment determination.

BILLING CODE 4120–01–P

TABLE 75: Proposed ASCQR Program Measure Set for the CY 2024 Reporting Period/CY 2026 Payment Determination

ASC #	CBE #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients**
ASC-11	1536†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel**

† CBE endorsement was removed.

* In the CY 2023 OPPS/ASC final rule (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years. In this proposed rule, we propose to standardize the surveys offered to patients pre- and post-surgery beginning with the CY 2024 reporting period/CY 2026 payment determination.

** In this proposed rule, we propose measure modifications to the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients and COVID-19 Vaccination Coverage Among HCP measures that begin with the CY 2024 reporting period/CY 2026 payment determination.

b. Summary of Previously Finalized and Newly Proposed ASCQR Program Quality Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination and Subsequent Years

Table 76 summarizes the previously finalized and newly proposed ASCQR Program measures for the CY 2025

[507] Ibid.

[508] Centers for Medicaid & Medicare Services. Hospital-Level, Risk-Standardized Improvement Rate in Patient-Reported Outcomes Following Elective Primary Total Hip and/or Total Knee Arthroplasty (THA/TKA). Available at: *https://cmit.cms.gov/cmit/#/FamilyView?familyId=1618.*

reporting period/CY 2027 payment determination.

TABLE 76: Proposed ASCQR Program Measure Set for the CY 2025 Reporting Period/CY 2027 Payment Determination

ASC #	CBE #	Measure Name
ASC-1	0263†	Patient Burn
ASC-2	0266†	Patient Fall
ASC-3	0267†	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant
ASC-4	0265†	All-Cause Hospital Transfer/Admission
ASC-7	None	ASC Procedure Volume (Previously referred to as ASC Facility Volume on Selected ASC Surgical Procedures)**
ASC-9	0658	Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients
ASC-11	1536†	Cataracts Visual Function (Previously referred to as Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery)*
ASC-12	2539	Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy
ASC-13	None	Normothermia Outcome
ASC-14	None	Unplanned Anterior Vitrectomy
ASC-15a	None	The Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) - About Facilities and Staff
ASC-15b	None	OAS CAHPS - Communication About Procedure
ASC-15c	None	OAS CAHPS - Preparation for Discharge and Recovery
ASC-15d	None	OAS CAHPS - Overall Rating of Facility
ASC-15e	None	OAS CAHPS - Recommendation of Facility
ASC-17	3470	Hospital Visits after Orthopedic Ambulatory Surgical Center Procedures
ASC-18	3366	Hospital Visits after Urology Ambulatory Surgical Center Procedures
ASC-19	3357	Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers
ASC-20	None	COVID-19 Vaccination Coverage Among Health Care Personnel
ASC-21	3636	Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM)***

† CBE endorsement was removed.
* In the CY 2023 OPPS/ASC final rule (87 FR 72118 through 72120), we finalized to keep data collection and submission voluntary for this measure for the CY 2025 reporting period and subsequent years.
** In this proposed rule, we propose to readopt the ASC Procedure Volume measure as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination.
*** In this proposed rule, we propose to adopt Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM) as a voluntary measure beginning with the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

BILLING CODE 4120–01–C

7. Maintenance of Technical Specifications for Quality Measures

We maintain technical specifications for previously adopted ASCQR Program measures. These specifications are updated as we modify the ASCQR Program measure set. The manuals that contain specifications for the previously adopted measures can be found on the CMS website (currently at: *https://qualitynet.cms.gov/asc/specifications-manuals).*[509] Our policy on maintenance of technical specifications for the ASCQR Program are codified in our regulations at § 416.325. We propose to amend our measure maintenance regulation at § 416.325(c) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other

[509] Qualitynet Home. (n.d.). Retrieved March 21, 2023, from *https://qualitynet.cms.gov/asc/specifications-manuals.*

conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

8. Public Reporting of ASCQR Program Data

We refer readers to the CYs 2012, 2016, 2017, and 2018 OPPS/ASC final rules (76 FR 74514 through 74515; 80 FR 70531 through 70533; 81 FR 79819 through 79820; and 82 FR 59455 through 59470, respectively) for detailed discussion of our policies regarding the public reporting of ASCQR Program data, which are codified in our regulations at § 416.315 (80 FR 70533).

We are not proposing any changes to these policies in this proposed rule.

C. Administrative Requirements

1. Requirements Regarding Data Submission

We refer readers to § 416.310(c)(1)(i) for our current policies regarding submission of data via our online data submission tool, including security official and system registration requirements. We propose to amend our collection and submission regulation at § 416.310(c)(1)(i) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

2. Requirements Regarding Program Participation

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75133 through 75135) for a complete discussion of the participation status requirements beginning with the CY 2014 payment determination. In the CY 2016 OPPS/ASC final rule (80 FR 70533 through 70534), we codified these requirements regarding participation status for the ASCQR Program in our regulations at § 416.305. We propose to amend our withdrawal regulation at § 416.305(b)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website,'' and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

D. Form, Manner, and Timing of Data Submitted for the ASCQR Program

Previously finalized quality measures and information collections discussed in this section were approved by the Office of Management and Budget (OMB) under control number 0938–1270 (expiration date August 31, 2025). An updated PRA package reflecting the updated information collection requirements related to the proposals set forth in this section of the proposed rule will be submitted for approval under the same OMB control number.

1. Data Collection and Submission

a. Background

We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

b. Requirements for Claims-Based Measures

(1) Requirements Regarding Data Processing and Collection Periods for Claims-Based Measures Using Quality Data Codes (QDCs)

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75135) for a complete summary of the data processing and collection periods for the claims-based measures using QDCs beginning with the CY 2012 reporting period/CY 2014 payment determination. In the CY 2016 OPPS/ASC final rule (80 FR 70534), we codified the requirements regarding data processing and collection periods for claims-based measures using QDCs for the ASCQR Program in our regulations at § 416.310(a)(1) and (2). We note that the previously finalized data processing and collection period requirements will apply to any future claims-based measures using QDCs adopted in the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

(2) Minimum Threshold, Minimum Case Volume, and Data Completeness for Claims-Based Measures Using QDCs

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59472) (and the previous rulemakings cited therein), as well as our regulations at §§ 416.310(a)(3) and 416.305(c) for our policies about minimum threshold, minimum case volume, and data completeness for claims-based measures using QDCs. We also refer readers to section XVI.D.1.b of the CY 2022 OPPS/ASC final rule (86 FR 63904 through 63905), where we finalized that our policies for minimum threshold, minimum case volume, and data completeness requirements apply to any future claims-based-measures using QDCs adopted in the ASCQR Program.

We are not proposing any changes to these policies in this proposed rule.

(3) Requirements Regarding Data Processing and Collection Periods for Non-QDC Based, Claims-Based Measure Data

We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59136 through 59138) for a complete summary of the data processing and collection requirements for the non-QDC based, claims-based measures. We codified the requirements regarding data processing and collection periods for non-QDC, claims-based measures for the ASCQR Program in our regulations at § 416.310(b). We note that these requirements for non-QDC based, claims-based measures apply to the following previously adopted measures:

- Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy; and
- Facility-Level 7-Day Hospital Visits after General Surgery Procedures Performed at Ambulatory Surgical Centers (CBE #3357).

We are not proposing any changes to these policies in this proposed rule.

c. Requirements for Data Submitted Via an Online Data Submission Tool

(1) Requirements for Data Submitted Via a CMS Online Data Submission Tool

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59473) (and the previous rulemakings cited therein) and our regulations at § 416.310(c)(1) for our requirements regarding data submitted via a CMS online data submission tool. We are currently using the HQR System (formerly referred to as the QualityNet Secure Portal) [510] to host our CMS online data submission tool, available by securely logging in at: *https://hqr.cms.gov/hqrng/login.* We note that, in the CY 2018 OPPS/ASC final rule (82 FR 59473), we finalized expanded submission via the CMS online tool to also allow for batch data submission and made corresponding changes at § 416.310(c)(1)(i).

- The following previously finalized measures require data to be submitted via a CMS online data submission tool beginning with the CY 2019 reporting period/CY 2021 payment determination: Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients;
- Cataracts Visual Function measure (Previously referred to as Cataracts:

[510] The HQR System was previously referred to as the QualityNet Secure Portal.

Improvement in Patients' Visual Function within 90 Days Following Cataract Surgery);

- Normothermia Outcome; and
- Unplanned Anterior Vitrectomy.

In the CY 2022 OPPS/ASC final rule (86 FR 63883 through 63885), we finalized our proposal to require and resume data collection beginning with the CY 2023 reporting period/CY 2025 payment determination for the following four measures:

- Patient Burn;
- Patient Fall;
- Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant; and
- All-Cause Hospital Transfer/Admission.

Measure data for these measures must be submitted via the HQR System.

Other than the proposal to amend § 416.310(c)(1)(i) and (d)(1) discussed in section XV.C.1 of this proposed rule, we are not proposing any changes to these policies in this proposed rule.

(a) Proposed Data Submission and Reporting Requirements for the ASC Procedure Volume Measure

In section XV.B.5.a of this proposed rule, we propose to re-adopt the ASC Procedure Volume measure (with modification), with voluntary reporting beginning with the CY 2025 reporting period followed by mandatory reporting beginning with CY 2026 reporting period/CY 2028 payment determination. We also propose that ASCs submit these data to CMS through the HQR System during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2025 reporting period, the data submission period would be January 1, 2026 to May 15, 2026, covering the performance period of January 1, 2025 to December 31, 2025.

Under this proposed measure, we will collect and publicly display data surrounding the top five most frequently performed procedures among ASCs in each of the following eight categories: Cardiovascular, Eye, Gastrointestinal, Genitourinary, Musculoskeletal, Nervous System, Respiratory, and Skin.[511] We will assess and update the top five procedures in each category annually as needed. We propose that ASCs would submit aggregate-level data through the CMS web-based tool (currently the HQR system). Data received through the HQR system website will then be publicly displayed on the data.cms.gov website, or other CMS website, following our 30-day preview period of submitted data.

We refer readers to our regulation at § 416.315 for our codified policies regarding public reporting of data under the ASCQR Program, as well as our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invite public comment on this proposal.

(b) Proposed Data Submission and Reporting Requirements for the Cataracts Visual Function Measure

In section XV.B.4.b of this proposed rule, we propose to modify the Cataracts Visual Function measure by standardizing acceptable survey instruments, beginning with the CY 2024 reporting period, which would limit the allowable survey instruments to those listed below:

- The National Eye Institute Visual Function Questionnaire-25 (NEI VFQ–25)
- The Visual Functioning Patient Questionnaire (VF–14)
- The Visual Functioning Index Patient Questionnaire (VF–8R)

We also propose that ASCs submit these data to CMS during the time period of January 1 to May 15 in the year prior to the affected payment determination year. For example, for the CY 2024 reporting period, the data submission period would be January 1, 2025 to May 15, 2025, covering the performance period of January 1, 2024 to December 31, 2024. Specifically, for data collection, we propose that ASCs submit aggregate-level data through the HQR System. We previously codified our existing policies regarding data collection and submission under the ASCQR Program in our regulations at § 416.310.

We invite public comment on this proposal.

(2) Requirements for Data Submitted Via a Non-CMS Online Data Submission Tool

We refer readers to the CY 2014 OPPS/ASC final rule (78 FR 75139 through 75140) and the CY 2015 OPPS/ASC final rule (79 FR 66985 through 66986) for our requirements regarding data submitted via a non-CMS online data submission tool (specifically, the CDC's National Health Safety Network [NHSN]). We codified our existing policies regarding the data collection periods for measures involving online data submission and the deadline for data submission via a non-CMS online data submission tool in our regulations at § 416.310(c)(2). While we did not finalize any changes to those policies in the CY 2022 OPPS/ASC final rule (86 FR 63875 through 63883), we did finalize policies specific to the COVID–19 Vaccination Coverage Among HCP measure, for which data will be submitted via the CDC NHSN. In section XV.B.4.a of this proposed rule, we discuss the proposed modification of the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The requirements for measure data submitted via the CDC NHSN website would remain as previously finalized.

We are not proposing any changes to these policies in this proposed rule.

d. Proposed Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In section XV.B.5.b of this proposed rule, we propose to adopt the THA/TKA PRO–PM into the ASCQR Program measure set. We also propose the reporting and submission requirements for PRO–PM measures as a new type of measure to the ASCQR Program.

(1) Submission of PRO–PM Data

(a) Data Submission Generally

We believe that ASCs should have the choice of selecting from multiple submission approaches, in line with input received by the measure developer during measure development and comments as summarized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45411 through 45414), which recommended that we provide multiple options for data submission mechanisms to ensure flexibility.

In section XV.B.5.b of this proposed rule, we propose that both ASCs and vendors use the HQR System for data submission for the THA/TKA PRO–PM, which would enable us to incorporate this new requirement into the infrastructure we have developed and use to collect other quality data. We would provide ASCs with additional detailed information and instructions for submitting data using the HQR System through CMS' existing websites, and through outreach, or both.

We invite public comment on these proposals.

[511] Ambulatory Surgical Center Specifications Manuals. Available at *https://qualitynet.cms.gov/asc/specifications-manuals#tab6.*

(2) Data Submission Reporting Requirements

(a) Data Submission Requirements for Measures Submitted via a Web-Based Tool

We refer readers to the QualityNet website available at: *https://qualitynet.cms.gov* for a discussion of the requirements for measure data submitted via the HQR System (formerly referred to as the QualityNet Secure Portal) for the CY 2017 payment determination and subsequent years. The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E, for more information regarding the HIPAA Privacy and Security Rules.

(b) Voluntary Reporting Requirements for the Proposed THA/TKA PRO–PM

For ASCs participating in voluntary reporting for the THA/TKA PRO–PM as discussed in section XV.B.5.b of this proposed rule, we propose that ASCs submit pre-operative PRO data, as well as matching post-operative PRO data, for at least 45 percent of their eligible elective primary THA/TKA procedures.

For the THA/TKA PRO–PM, we propose that the first voluntary reporting period for the CY 2025 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2025 through December 31, 2025) and post-operative PRO data collection from 300 to 425 days after the procedure. Therefore, during this first voluntary reporting period for CY 2025, ASCs would submit pre-operative data by May 15, 2026 and post-operative data by May 15, 2027, and we intend to provide ASCs with their results in confidential feedback reports in CY 2028. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive order would be extended to the first day thereafter. After the initial submission of pre-operative data for the first voluntary period, ASCs would submit both pre-operative and post-operative data by the same day, but for different time periods. For example, ASCs would need to submit: (1) post-operative data for the first voluntary reporting period (for procedures performed between January 1, 2025 and December 31, 2025); and (2) pre-operative data for the second voluntary reporting (for procedures performed between January 1, 2026 and December 31, 2026) of the THA/TKA PRO–PM by May 15, 2027.

For the THA/TKA PRO–PM, we propose that the second voluntary reporting period for the CY 2026 reporting period would include pre-operative PRO data collection from 90 to 0 days before the procedure (for eligible elective THA/TKA procedures performed from January 1, 2026, through December 31, 2026) and post-operative PRO data collection from 300 to 425 days after the procedure. ASCs would submit pre-operative data by May 15, 2027 and post-operative data by May 15, 2028, and we intend to provide ASCs with their results in confidential feedback reports in CY 2029. ASCs that voluntarily submit data for this measure would receive confidential feedback reports that detail submission results from the reporting period. Results of voluntary reporting would not be made publicly available. If feasible, we would calculate and provide each participating ASC with their RSIR as part of the confidential feedback reports. This would provide each ASC with an indication of their performance relative to the other facilities that participate in the voluntary reporting period.

While we do not propose to publicly report the data we receive during the voluntary reporting periods for the THA/TKA PRO–PM facility-level RSIR, we propose to publicly report which ASCs choose to participate in voluntary reporting and/or the percent of pre-operative data submitted by participating ASCs for the first voluntary reporting period, and their percent of pre-operative and post-operative matched PRO data submitted for subsequent voluntary reporting periods. For example, if out of 100 eligible procedures a facility submits 45 pre-operative cases that match to post-operative cases, then we would report that facilities submitted 45 percent of matched pre-operative and post-operative PRO surveys during voluntary reporting.

We refer readers to Table 77 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the voluntary reporting periods for THA/TKA PRO–PM.

TABLE 77: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM VOLUNTARY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Confidential Reporting
Voluntary Reporting CY 2025	January 1, 2025-December 31, 2025	October 3, 2024-December 31, 2025	May 15, 2026	October 28, 2025-March 1, 2027	May 15, 2027*	CY 2028**
Voluntary Reporting CY 2026	January 1, 2026-December 31, 2026	October 3, 2025-December 31, 2026	May 15, 2027*	October 28, 2026-February 29, 2028	May 15, 2028	CY 2029**

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive order would be extended to the first day thereafter.

**Public reporting of information on facility participation in the voluntary reporting periods would occur in CY 2028 for the CYs 2025 and 2026 reporting periods.

(c) Mandatory Reporting

Following the two voluntary reporting periods, we propose that mandatory reporting of the THA/TKA PRO–PM would begin with reporting PRO data for eligible elective THA/TKA procedures from January 1, 2027 through December 31, 2027 (the CY 2027 performance period), impacting the CY 2030 payment determination. This initial mandatory reporting would include pre-operative PRO data collection from 90 days preceding the applicable performance period and from 300 to 425 days after the performance period. For example, pre-operative data from October 3, 2026 through December 31, 2027 (for eligible elective primary THA/TKA procedures from January 1, 2027 through December 31, 2027) and post-operative PRO data collection from October 28, 2027 to February 28, 2029. Pre-operative data submission would occur by May 15, 2028 and post-operative data submission in May 15, 2029.

We intend to provide ASCs with their results in CY 2030 before publicly reporting results on the Compare tool hosted by HHS, currently available at *https://www.medicare.gov/care-compare*, or its successor website. We would provide confidential feedback reports during the voluntary period which would include the RSIR as well as other results that support understanding of their performance prior to public reporting. For this first mandatory reporting period, facilities that fail to meet the reporting requirements would receive a reduction of their Annual Payment Update (APU) in the CY 2030 payment determination. We propose that ASCs would be required to submit 45 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data as a minimum amount of data for mandatory reporting in the ASCQR Program.

We refer readers to Table 78 for an overview of the proposed performance period, pre- and post-operative data collection timeframes, and data submission deadlines during the first mandatory reporting period.

TABLE 78: PRE-OPERATIVE AND POST-OPERATIVE PERIODS FOR THA/TKA PRO-PM FOR MANDATORY REPORTING

Reporting Cycle	Performance Period	Pre-Procedure Data Collection (0 to 90 days before the procedure)	Pre-Procedure Data Submission Date	Post-Procedure Data Collection (300 to 425 days after the procedure)	Post-Procedure Data Submission	Confidential Reporting
Mandatory Reporting CY 2027	January 1, 2027-December 31, 2027	October 3, 2026-December 31, 2027	May 15, 2028	October 28, 2027-February 28, 2029	May 15, 2029	CY 2030*

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for federal employees by statute or Executive order would be extended to the first day thereafter. Public reporting of information on facility results in the mandatory reporting period would occur in CY 2030 for CY 2027 reporting period/CY2030 payment determination.

We invite comment on these proposals.

e. ASCQR Program Data Submission Deadlines

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191) for a detailed discussion of our data submission deadlines policy, which we codified in our regulations at § 416.310(f).

We are not proposing any changes to this policy in this proposed rule.

f. Review and Corrections Period for Measure Data Submitted to the ASCQR Program Review and Corrections Period for Data Submitted via a CMS Online Data Submission Tool

We refer readers to the CY 2021 OPPS/ASC final rule (85 FR 86191 through 86192) for a detailed discussion of our review and corrections period policy, which we codified in our regulations at § 416.310(c)(1)(iii).

We are not proposing any changes to this policy in this proposed rule.

g. ASCQR Program Reconsideration Procedures

We refer readers to the CY 2016 OPPS/ASC final rule (82 FR 59475) (and the previous rulemakings cited therein) and § 416.330 for the ASCQR Program's reconsideration policy.

We are not proposing any changes to this policy in this proposed rule.

h. Extraordinary Circumstances Exception (ECE) Process

We refer readers to the CY 2018 OPPS/ASC final rule (82 FR 59474 through 59475) (and the previous rulemakings cited therein) and § 416.310(d) for the ASCQR Program's extraordinary circumstance exceptions (ECE) request policy. We propose to amend our exception policy codified at § 416.310(d)(1) to replace references to ''QualityNet'' with ''CMS-designated information system'' or ''CMS website'', and to make other conforming technical edits, to accommodate recent and future systems requirements and mitigate confusion for program participants.

We invite public comment on this proposal.

E. Payment Reduction for ASCs That Fail To Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail To Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2022, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update is the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023). Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0 percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0 percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed

in Addenda AA and BB to the proposed rule, which are available via the internet on the CMS website): ''A2'', ''G2'', ''P2'', ''R2'' and ''Z2'', as well as the service portion of device-intensive procedures identified by ''J8'' (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed above would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators ''A2'', ''G2'', ''J8'', ''P2'', ''R2'' and ''Z2.'' These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2023 OPPS/ASC final rules with comment period we did not make any other changes to these policies. We propose the continuation of these policies for the CY 2024 reporting period/CY 2026 payment determination.

XVI. Proposed Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background

1. Overview

The Rural Emergency Hospital Quality Reporting (REHQR) Program's overarching goals are to improve the quality of care provided to Medicare beneficiaries, facilitate public transparency, ensure accountability, and safeguard the accessibility of facilities in rural settings. We refer readers to section XVI of the CY 2023 Hospital Outpatient Prospective Payment System (OPPS)/Medicare Ambulatory Surgical Center Payment System (ASC) final rule (87 FR 72136 through 72150) for an overview of the REHQR Program.

2. Statutory and Regulatory History of Quality Reporting for REHs

Congress established Rural Emergency Hospitals (REHs) as a new Medicare provider type in the Consolidated Appropriations Act (CAA), 2021. Section 125 of Division CC of the CAA added section 1861(kkk) to the Social Security Act (the Act). This section defines an REH as a facility that, in relevant part, was, as of December 27, 2020 (1) a critical access hospital (CAH); or (2)(i) a subsection (d) hospital with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area,[512] or (ii) a subsection (d) hospital with not more than 50 beds that was treated as being in a rural area.[513] [514] Among other requirements, an REH must apply for enrollment in the Medicare program, provide emergency department (ED) services and observation care, and not provide any acute care inpatient services (other than post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility).[515] [516] At the election of the REH, it can also provide certain services furnished on an outpatient basis.[517]

3. Proposal To Codify the Statutory Authority of the REHQR Program

We propose to codify the statutory authority for the REHQR Program at 42 CFR 419.95 by adding paragraph (a) ''Statutory Authority.'' Section 1861(kkk)(7)(A) of the Act authorizes the Secretary to implement a quality reporting program requiring REHs to submit data on measures in accordance with the Secretary's requirements in section 1861(kkk)(7). Section 1861(kkk)(7)(B)(ii) requires REHs to submit quality measure data to the Secretary ''in a form and manner, and at a time, specified by the Secretary.'' The Act does not require the Secretary to provide incentives for submitting this

[512] As defined in section 1886(d)(2)(D) of the Act.

[513] Pursuant to section 1886(d)(8)(E) of the Act.

[514] As set out under section 1861(kkk)(3) of the Act.

[515] 42 CFR part 485 subpart E (§§ 485.500 through 485.546).

[516] Qualification Requirements for REHs are set out under section 1861(kkk)(2) of the Act.

[517] *See* section 1861(kkk)(1)(A)(ii) of the Act.

data under the REHQR Program, nor does it require the Secretary to impose penalties for failing to comply with this requirement under the REHQR Program.

We invite public comment on this proposal.

B. REHQR Program Quality Measures

1. Considerations in the Selection of REHQR Program Quality Measures

As we stated in the CY 2023 OPPS/ASC final rule, we seek to adopt a concise set of important, impactful, reliable, accurate, and clinically relevant measures for REHs that would inform consumer decision-making regarding care and drive further quality improvement efforts in the REH setting (87 FR 72137). As we considered potential measures for the REHQR Program, we prioritized measures that had undergone previous consensus-based entity (CBE) [518] review for the hospital outpatient department setting that reflect important areas of service for REHs while adhering to the CMS National Quality Strategy goals,[519] Strategic Plan,[520] Meaningful Measures 2.0 initiatives,[521] and the Department of Health and Human Services' (HHS) Strategic Plan.[522] When identifying potential measures for the REHQR Program, we focused on the considerations of service and patient volume, care accountability and quality, rurality and setting relevance, and health equity.

We note that under section 1861(kkk)(7)(C)(i) of the Act, unless the exception of subclause (ii) applies, a measure selected for the REHQR Program must have been endorsed by the entity with a contract under section 1890(a) of the Act, also known as the CBE. The CBE is a voluntary, consensus-based, standard-setting organization with a diverse representation of consumer, purchaser, provider, academic, clinical, and other health care stakeholder organizations. The CBE was established to standardize healthcare quality measurement and reporting through its consensus development processes. We have generally adopted CBE-endorsed measures in our reporting programs. However, section 1861(kkk)(7)(C)(ii) provides an exception to CBE-endorsement, which is that, in the case of a specified area or medical topic determined appropriate by the Secretary for which a 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 endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In general, we prefer to adopt measures that have been endorsed by the CBE identified by the Secretary; however, due to lack of an endorsed measure for a given setting, procedure, or other aspect of care, the requirement that measures reflect consensus among affected parties can be achieved in other ways, including input from the measure development process, through broad acceptance, use of the measure(s) in other programs, and through public comment.

We propose to adopt four measures in this proposed rule: (1) Abdomen Computed Tomography (CT)—Use of Contrast Material; (2) Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery—for the REHQR Program measure set. The proposed measures are currently adopted measures in the Hospital Outpatient Quality Reporting (OQR) Program. We recognize REHs will be smaller hospitals that will likely have limited resources compared with larger hospitals in metropolitan areas.[523] For the REHQR Program, we intend to seek balance between the costs associated with reporting data and the benefits of ensuring safety and quality of care through measurement and public reporting. Because REHs will consist of hospitals formerly operating as either CAHs or subsection (d) hospitals, we assessed whether these facilities have successfully reported the proposed measures within the context of the Hospital OQR Program with sufficient volume to meet CMS case number thresholds for data to be publicly reported. We note that CAHs report data voluntarily under the Hospital OQR Program. We considered reporting rates and measure performance for subsection (d) hospitals that are eligible to convert to REHs and also analyzed data for other subsection (d) hospitals that are not eligible for conversion to permit comparisons of these providers' ability to report these data in sufficient numbers to permit public reporting and to view comparative performance. Table 79 includes the results of this analysis.

BILLING CODE 4120–01–P

[518] 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.

[519] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. Last accessed April 13, 2023.

[520] CMS (2023). CMS Strategic Plan. Available at: *https://www.cms.gov/cms-strategic-plan*. Last accessed March 10, 2023.

[521] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*. Last accessed April 13, 2023.

[522] HHS (2022). Strategic Plan FY 2022–2026. Available at *https://www.hhs.gov/about/strategic-plan/2022-2026/index.html*. Last accessed March 10, 2023.

[523] American Hospital Association, Rural Report. (February, 2019), 2019 Challenges Facing Rural Communities and the Roadmap to Ensure Local Access to High-quality, *Affordable Care 3*. Available at *https://www.aha.org/system/files/2019-02/rural-report-2019.pdf*. Last accessed February 28, 2023.

TABLE 79: Number of Hospitals Publicly Reporting Measures Proposed for the REHQR Program

Abdomen Computed Tomography (CT) - Use of Contrast Material*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,060 (77.9%)	151 (75.5%)	146 (48.7%)	500 (89.9%)	2,060 (93.8%)
Mean (CT studies)	6.3	7.5	7.4	6.4	6.0
10th Percentile	1.7	2.4	0.6	1.7	1.4
25th Percentile	2.9	4.2	2.2	3.2	3
Median	5	6.5	4.7	5.35	5.1
75th Percentile	7.8	10.1	8.1	8.15	7.9
90th Percentile	12.1	14	12.7	11.7	11

*Ratio of CT abdomen studies that are performed both with and without contrast of all CT abdomen studies performed. Lower scores indicate better performance.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients – Overall Rate*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,126 (82.7%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2 ,081 (94.7%)
Mean (minutes)	125.9	130.0	142.5	156.7	193.6
10th Percentile	91	99	97	111	138
25th Percentile	106	109	113	130	160
Median	123	130	137	153	188
75th Percentile	142	148	169	179	219
90th Percentile	164	159	197	204	254

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients - Reported Measure, Excluding Psychiatric/Mental Health and Transfer Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	1,124 (82.6%)	163 (81.5%)	173 (57.7%)	507 (91.2%)	2,078 (94.6%)
Mean (minutes)	118.5	122.6	137.0	150.6	188.0
10th Percentile	86	94	92	106	133
25th Percentile	100	104	110	125	155
Median	116	122	132	148	183
75th Percentile	134	140	159	172	214
90th Percentile	153	153	191	199	248

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Psychiatric/Mental Health Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	703 (51.7%)	128 (64.0%)	87 (29.0%)	419 (75.4%)	1,869 (85.1%)
Mean (minutes)	213.1	208.6	265.9	267.8	340.9
10th Percentile	118	119	120	142	174
25th Percentile	148	143.5	169	181	226
Median	190	187.5	230	232	294
75th Percentile	243	237	312	315	395
90th Percentile	333	330	444	406	552

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Median Time from ED Arrival to ED Departure for Discharged ED Patients - Transfer Patients*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total Eligible)	934 (68.6%)	145 (72.5%)	119 (39.7%)	384 (69.1%)	681 (31.0%)
Mean (minutes)	259.4	300.6	321.7	315.2	366.3
10th Percentile	162	186	201	210	236
25th Percentile	194	214	249	247	276
Median	242	256	300	299.5	341
75th Percentile	301	311	376	360.5	422
90th Percentile	385	387	486	439	519

*Rate is time in minutes from ED arrival to ED departure for patients discharged from the ED. Lower values indicate better performance. This measure is stratified by four category types of patients.

Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery* Excluding Eye Surgery and Routine Colonoscopy					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	182 (13.4%)	78 (39.0%)	184 (61.3%)	403 (72.5%)	1,939 (88.3%)
Mean (ratio of predicted to expected visits)	1.006	1.024	0.988	1.016	1.010
10th Percentile	0.9	0.9	0.8	0.9	0.8
25th Percentile	0.9	1	0.9	0.9	0.9
Median	1	1	1	1	1
75th Percentile	1	1.1	1.1	1.1	1.1
90th Percentile	1.1	1.2	1.2	1.2	1.2

*Ratio of "predicted" unplanned hospital visits to the number of "expected" unplanned hospital visits. Lower scores indicate better performance.

Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Rate*					
Statistic	**Critical Access Hospitals**	**Subsection (d) hospitals with ≤ 50 beds Rural Only**	**Subsection (d) hospitals with ≤ 50 beds Urban Only**	**Subsection (d) hospitals with 51 -100 beds**	**Subsection (d) hospitals with >100 beds**
Total Number of Hospitals	1,361	200	300	556	2,197
Number Reporting (% of Total)	609 (44.7%)	131 (65.5%)	131 (43.7%)	465 (83.6%)	1,945 (88.5%)
Mean (visits)	14.3	14.4	14.3	14.3	14.2
10th Percentile	13.6	13.4	13.2	13	12.7
25th Percentile	13.8	13.8	13.7	13.6	13.4
Median	14.2	14.2	14.2	14.2	14.1
75th Percentile	14.6	15	14.8	14.9	14.9
90th Percentile	15.1	15.6	15.6	15.7	15.7

*Rate is the number of unplanned hospital visits after colonoscopy (per 1,000 colonoscopies). Lower scores indicate better performance.

Data sources: Program Resource System (PRS) accessed January 10, 2023, Care Compare data updated each January 2018-2023, and CMS Providers of Services File (PSF) - Hospital & Non-Hospital Facilities Q3 2022.

Includes all data submitted for all CAHs and subsection (d) hospitals open as of December 27, 2020.

Hospitals are considered eligible to report in Care Compare if they have a Medicare accept date prior to the latest measure end date and are open as of the PRS accessed date. March 31, 2022 is the measure end date for Hospital OQR Program measures for public reporting in the January 2023 Care Compare refresh.

Hospitals are considered reporting Hospital OQR Program measures if they have a score published on Care Compare. Requirements for publication include that aggregated case numbers reported be greater than or equal to 10. The published data value must not be "Not Available".

Rural/urban location is identified by the CMS PSF - Hospital & Non-Hospital Facilities Q3 2022. Rural/urban location is based on Core Based Statistical Area (CBSA), which indicates whether the county is defined as urban or rural to limit the analysis to areas currently viewed as rural.

Hospital bed size is the number of total Medicare certified beds listed in PRS.

BILLING CODE 4120–01–C

Based on our analysis of these data, current to the January 2023 refresh of Care Compare, we note that a relatively high percentage of the hospitals eligible to convert to REH status have reported aggregated measure data in sufficient number for disclosure per CMS privacy policy [524] for the measures we propose for the initial REHQR Program measure set. For example, in comparing solely the averages for the Abdomen Computed Tomography (CT)—Use of Contrast Material measure, a significant majority of CAHs (77.9 percent) and rural subsection (d) hospitals with 50 or fewer beds (75.5 percent) have data publicly reported. In addition, for the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure, rural subsection (d) hospitals with 50 or fewer beds were more often able to have data publicly reported than urban subsection (d) hospitals with 50 or fewer beds (65.5 percent versus 43.7 percent), which indicates that this measure could be useful for small rural hospitals that convert. For this latter measure, while the mean values are similar across categories of hospitals, the results show that there are outlier hospitals with higher levels of hospital events following outpatient surgery than expected, which provides potentially valuable information when discerning individual hospital performance.

While it is not possible to identify the exact group of hospitals that will choose to convert to REH status, our analysis indicates that the services targeted by the proposed measures are relevant for hospitals that may participate in the REHQR Program as these hospitals are currently providing the services assessed by the selected measures with case volumes sufficient to meet thresholds to allow public reporting of the collected data.[525]

2. Retention of Measures Previously Adopted Into the REHQR Program

a. Background

For purposes of our quality reporting programs, we retain measures from previously adopted measure sets for subsequent years unless otherwise specified; for example, see the Hospital OQR (42 CFR 419.46(i)(1)) and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs (§ 416.320(a)). As this approach establishes regularity and predictability for participating providers and suppliers, we seek to align the REHQR Program with this policy.

[524] CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

[525] CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases. See CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4.

b. Proposal To Adopt and Codify a Measure Retention Policy for the REHQR Program

We propose that once adopted into the REHQR Program measure set, such measures are retained for use until we propose removal, suspension, or replacement. We also propose to codify this policy at § 419.95 by adding paragraph (e) ''Retention and Removal of Quality Measures Under the REHQR Program.'' In proposed paragraph (e)(1), we propose that quality measures would be adopted into the REHQR Program measure set until such time that such measures are proposed for removal, suspension, or replacement, as set forth at proposed paragraphs (e)(2) and (e)(3) of the section.

We invite public comment on these proposals.

3. Removal of Quality Measures From the REHQR Program Measure Set

a. Proposal To Adopt and Codify an Immediate Removal Policy for Adopted REHQR Program Measures

When there is reason to believe that the continued collection of a measure as currently specified raises potential patient safety concerns, we believe it would be appropriate for us to take immediate action to remove the measure from the REHQR Program outside of rulemaking. Therefore, we propose to adopt an immediate measure removal policy that would allow us to promptly remove such a measure and notify REHs and the public of the decision to remove the measure through standard hospital communication channels, including, but not limited to, REHQR Program-specific listservs and REHQR Program guidance currently housed on the QualityNet website. We also propose to confirm the removal of the measure in the next appropriate rulemaking, typically an OPPS rulemaking cycle. We note that the Hospital OQR Program previously finalized a similar policy (74 FR 60634 through 60635).

We propose to codify this policy at § 419.95 by adding paragraph (e)(2) ''Immediate Measure Removal.'' In proposed paragraph (e)(2), we propose that in cases where CMS believes that the continued use of a quality measure as specified raises patient safety concerns, CMS would immediately remove the measure from the REHQR Program, promptly notify REHs and the public of the removal of the measure and the reasons for its removal, and confirm the removal of the measure in the next appropriate rulemaking.

We invite public comment on these proposals.

b. Proposal To Adopt and Codify a Measure Removal Factors Policy

The Hospital OQR and ASCQR Programs use similar sets of factors for determining whether to remove measures. For more detail on the measure removal factors in those programs, we refer readers to §§ 419.46(i)(3)(i) and 416.320(c)(2), respectively. Generally, we prefer to use similar removal factors across the quality reporting programs for consistency and alignment. Therefore, to enhance alignment with those programs, we propose to adopt a similar set of removal factors for the REHQR Program.

Specifically, we propose to adopt the following eight factors to determine conditions for measure removal from the REHQR Program:

- Factor 1. Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures).
- Factor 2. Performance or improvement on a measure does not result in better patient outcomes.
- Factor 3. A measure does not align with current clinical guidelines or practice.
- Factor 4. The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic.
- Factor 5. The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.
- Factor 6. The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.
- Factor 7. Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.
- Factor 8. The costs associated with a measure outweigh the benefit of its continued use in the program.

In addition, for the proposed Measure Removal Factor 1, we propose that a measure for the REHQR Program would be deemed topped-out by determining: (1) when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of all measure data reported for all REHs, and (2) when the measure's truncated coefficient of variation (TCOV) is less than or equal to 0.1.

We propose to codify these policies at § 419.95 by adding paragraph (e)(3), ''Measure Removal, Suspension, or Replacement Through the Rulemaking Process.'' In proposed paragraph (e)(3), we propose that unless a measure raises specific safety concerns as set forth in proposed paragraph (e)(2) of the section, we would use rulemaking to remove, suspend, or replace quality measures in the REHQR Program. We also propose to adopt the eight removal factors discussed above by codifying them at proposed paragraph (e)(3)(i), in alignment with other quality reporting programs (74 FR 60634 through 60635, 77 FR 68472, and 83 FR 59082). Additionally, we propose to adopt the criteria to determine topped-out measures discussed above at proposed paragraph (e)(3)(ii). Similar to the Hospital OQR Program (79 FR 66941 through 66942), we propose to assess the benefits of removing a measure from the REHQR Program on a case-by-case basis at proposed paragraph (e)(3)(iii). An REHQR Program measure would not be removed solely based on meeting any specific factor.

We invite public comment on these proposals.

4. Modifications to Previously Adopted Measures

a. Background

It is important for measures adopted for the REHQR Program to remain up-to-date. We believe the way to achieve this is to have in place a sub-regulatory process to incorporate non-substantive updates to measure specifications to facilitate the incorporation of scientific advances and updates to measure specifications in a as timely manner as possible.

b. Proposal To Adopt and Codify a Sub-Regulatory Measure Modification Policy

We propose a policy under which we would use a sub-regulatory process to make non-substantive updates to measures adopted for the REHQR Program. Examples of non-substantive changes to measures might include updated diagnoses or procedure codes. With respect to what constitutes substantive versus non-substantive changes, we expect to make this determination on a case-by-case basis.

We propose that when there is an update to an REHQR Program measure that we believe does not substantially change the nature of the measure, we would use a sub-regulatory process to incorporate those updates to the measure specifications that we apply to the program. Specifically, we will develop a specifications manual that will provide the complete and current technical specifications and abstraction information for quality measures used in the REHQR Program. We would

revise the specifications manual to clearly identify any updates, and would provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary. We would also provide notification of the measure specification updates on a designated website, currently the QualityNet website, *https://qualitynet.cms.gov/*. We note that this proposed policy for the REHQR Program aligns with the policies under the Hospital OQR Program (73 FR 68766 through 68767) and ASCQR Program (§ 416.325) that allow measures to be refined through a sub-regulatory process.

We propose to codify this policy at § 419.95(d) ''Technical Specifications and Measure Maintenance Under the REHQR Program.'' In proposed paragraph (d)(2), we propose that REHQR Program specifications would be updated based on whether the change is considered substantive or non-substantive, as determined by CMS. In proposed paragraph (d)(2)(ii), we propose that if CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS would use a sub-regulatory process to revise the specifications manual as discussed above.

Changes that we determine to be substantive would be those in which the changes are so significant that the measure is no longer the same measure. In proposed paragraph (d)(2)(i), we propose that we would utilize rulemaking to adopt substantive updates to measures previously adopted under the REHQR Program. We believe that this proposal adequately balances the need to incorporate updates to the REHQR Program measures in the most expeditious manner possible to maintain relevancy, reliability, and accuracy of data collection while also preserving the public's ability to comment on updates that significantly change a measure.

We invite public comment on these proposals.

c. Proposal To Develop and Maintain Technical Specifications for Quality Measures

We intend to maintain technical specifications for adopted REHQR Program measures. We note that many of the measures considered for the REHQR Program have been previously adopted by the Hospital OQR Program. To simplify and streamline participation in the REHQR Program, we propose to adopt a policy for maintaining the measure specifications of REHQR Program measures that aligns with the Hospital OQR Program's policy (83 FR 59104 through 59105).

In this proposed rule, we propose that, whenever we modify the REHQR Program measures and measure sets, we would also update the specifications manual for the REHQR Program. The manuals containing specifications for previously adopted measures can be found on the QualityNet website at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. At proposed paragraph (d)(1) of § 419.95, ''Technical Specifications and Measure Maintenance Under the REHQR Program,'' we propose to update the specifications manual for REHQR Program measures at least every 12 months beginning with CY 2024.

We invite public comment on this proposal.

5. Proposed New Measures for the REHQR Program Measure Set

In this proposed rule, we propose to adopt four measures into the REHQR Program measure set beginning CY 2024: (1) Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Three of these measures would be calculated from Medicare Fee-For-Service (FFS) claims and enrollment information. The fourth is a chart-abstracted measure. Many hospitals that are eligible to convert to REH status would already have established resources and experience with submitting these four measures as part of the Hospital OQR Program as previously discussed.

a. Proposal To Adopt the Abdomen Computed Tomography (CT)—Use of Contrast Material Measure

(1) Background

A CT study performed with and without contrast increases the radiation dose to patients,[526] exposing them to the potential harmful side effects of the contrast material itself[527] and it is often unnecessary.[528] In the past, reports showed deviations from clinically appropriate American College of Radiology contrast practices for abdominal/pelvic CTs nationally.[529] A 2020 study using CMS Care Compare data determined that hospitals are now conducting fewer duplicate abdomen CTs (that is, less often performing CTs twice, once with and once without contrast). These improvements are more pronounced among hospitals that formerly conducted the most duplicate abdomen CTs. The reduction in duplicate abdomen CTs observed in the 2020 study may indicate that the Abdomen Computed Tomography (CT)—Use of Contrast Material measure (the Abdomen CT) measure has been effective in identifying performance gaps among some hospitals. Thus, collecting data on this measure may have been effective in reducing duplicate abdomen CTs and lowering related patient risks.[530] However, the same 2020 study found that duplicate abdomen CTs continue to occur.

We believe that the Abdomen CT measure is relevant for REH quality reporting. Although analysis of Care Compare data indicate the practice of duplicate scans continues with some hospitals large and small in both rural and urban settings, rural hospitals during the study period accounted for nearly half of those cases.[531] We note that this measure is also part of the Hospital OQR Program's measure set (adopted in the CY 2009 OPPS/ASC final rule (73 FR 68766)).

(2) Measure Overview

This measure provides the percentage of CT abdomen and abdominopelvic studies performed with and without contrast out of all CT abdomen studies performed (those without contrast, those with contrast, and those with both).

[526] Sahbaee, P, et. al (2017). The Effect of Contrast Material on Radiation Dose at CT: Part II. A Systematic Evaluation across 58 Patient Models. Radiology, 283(3), 749–757. *https://doi.org/10.1148/radiol.2017152852*.

[527] An, J, et. al. (2019). Differences in Adverse Reactions Among Iodinated Contrast Media: Analysis of the KAERS Database. The Journal of Allergy and Clinical Immunology: In Practice, 7(7), 2205–2211. *https://www.sciencedirect.com/science/article/abs/pii/S2213219819302570*.

[528] Hwang, IK, Lee, YS, Kim, J, Lee, YJ, Park, JH, Hwang. (2015). Do we really need additional contrast-enhanced abdominal computed tomography for differential diagnosis in triage of middle-aged subjects with suspected biliary pain. *Medicine*, 94(7):e546. doi: 10.1097/MD.0000000000000546.

[529] Broder JS, Hamedani AG, Liu SW, Emerman CL. (2013). Emergency department contrast practices for abdominal/pelvic computed tomography—a national survey and comparison with the American College of Radiology Appropriateness Criteria(®). *J Emerg Med*, 44(2): 423–433. Available at: *https://doi.org/10.1016/j.jemermed.2012.08.027*. Last accessed February 28, 2023.

[530] Davis, M, McKiernan, C, Lama, S, Parzynski, C, Bruetman, C, & Venkatesh, A., (July, 2020). Trends in publicly reported quality measures of hospital imaging efficiency, 2011–2018. *American Journal of Roentology* 215: 153–158. Available at *https://www.ajronline.org/doi/pdf/10.2214/AJR.19.21993*. Last accessed April 3, 2023.

[531] Ibid.

Section 1890A(a)(2) of the Act outlines the pre-rulemaking process established under section 1890A of the Act, which requires the Secretary to make available to the public by December 1 of each year a list of quality and efficiency measures under consideration. The Abdomen CT measure was on the 2022 Measures Under Consideration (MUC) list,[532] and the Measure Applications Partnership (MAP) Hospital Workgroup provided conditional support for this measure to be included in rulemaking for the REHQR Program. The MAP provides an annual review of the MUC list, and presents CMS with its recommendations in its Final Recommendations.[533] In its February 1, 2023 Final Recommendations, the MAP noted that the measure addresses a critical priority of patient safety in rural hospitals for the REHQR Program.[534] In the Final Recommendations, the MAP noted that the Health Equity Advisory Group expressed the importance of the measure and its potential to advance health equity, and the Rural Health Advisory Group discussed the measure in detail and cited no concerns with regard to rural health. The MAP conditionally supported the measure for rulemaking, pending testing indicating the measure is reliable and valid, and having CBE endorsement.[535]

Although section 1861(kkk)(7)(C)(i) of the Act requires that measures specified by the Secretary for use in the REHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(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. The Abdomen CT measure is not CBE endorsed and we were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure. Also, we believe the measure has received sufficient support from consensus organizations, given the conditional support for the measure by the MAP Hospital Workgroup,[536] favorable comments received by the Health Equity Advisory Group,[537] and lack of objection by the Rural Health Advisory Group.[538]

We propose to adopt the Abdomen CT measure into the REHQR Program measure set beginning with the CY 2024 reporting period. By addressing the critical priority area of patient safety in rural hospitals, collecting data on this measure seeks to ensure that CT abdomen imaging in rural communities adheres to evidence-based clinical guidelines. Inclusion of this measure aligns with the CMS National Quality Strategy goals of embedding quality into the care journey, as well as the goal of promoting safety,[539] and is aligned with the priorities we identified for our Meaningful Measures 2.0 initiative, including using only high-value quality measures that impact key quality domains and aligning measures across our programs.[540]

(3) Data Sources

This measure addresses excessive radiation exposure from improper outpatient imaging procedures in Medicare beneficiaries. It would be calculated using Medicare FFS final action claims and enrollment data for hospital services paid through the OPPS for abdomen CT studies performed in the REH setting. Data from the hospital outpatient file is used to determine beneficiary inclusion (for example, a CT abdomen study performed at an REH) and exclusion (that is, diagnoses of adrenal mass, hematuria, infections of the kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of bladder, malignant neoplasm of pancreas, diseases of urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorder of kidney or ureter).[541]

(4) Measure Calculation

This measure calculates the percentage of CT abdomen and abdominopelvic studies that are performed with and without contrast out of all CT abdomen studies performed (those with contrast, those without contrast, and those with both). The measure would be calculated based on a 12-month window of claims data. From this patient cohort, the numerator contains patients who had a combined CT abdomen study (that is, a CT abdomen study without contrast followed by a CT abdomen study with contrast, documented using the CT Abdomen With and Without Contrast CPT code). For this measure, lower scores indicate less usage of CT scanning as scans with and without contrast are typically not medically necessary, which means a high-performing facility reports a value nearer to zero, whereas facilities that may be performing too many combined CT abdomen studies score closer to 100 percent.[542]

(5) Cohort

This measure would apply to Medicare beneficiaries enrolled in original, Medicare FFS who underwent an abdomen or abdominopelvic CT study with or without contrast performed at an REH. This measure does not include Medicare managed care beneficiaries, non-Medicare patients, or beneficiaries who were admitted to the hospital as inpatients. A beneficiary can be included in the measure's initial patient population multiple times because each abdomen or abdominopelvic CT (without contrast, with contrast, or both with and without contrast) performed at an REH during the data collection period is counted once in the measure's denominator.

This claims-based imaging measure is not risk-adjusted; instead, Medicare FFS beneficiaries who have a clinical diagnosis of one or more conditions for which imaging with and without contrast is considered appropriate are

[532] Centers for Medicare & Medicaid Services (CMS). 2022 Measures Under Consideration Spreadsheet. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[533] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[534] Centers for Medicare & Medicaid Services (CMS). *2022–2023 MAP Final Recommendations.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed April 13, 2023.

[535] Ibid.

[536] CMS, 2022 Measures Under Consideration Spreadsheet.

[537] CMS, 2022–2023 MAP Final Recommendations.

[538] Ibid.

[539] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* Last accessed April 13, 2023.

[540] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* Last accessed April 13, 2023.

[541] YNHHSC/CORE and The Lewin Group, 2021. *Abdomen Computed Tomography (CT)—Use of Contrast Material (OP–10): 2021 Annual Reevaluation Report.* Available at: *https://qualitynet.cms.gov/files/607ee75eaba8620022335d7e?filename=OP=10_2021_ReevalReport.pdf.* Last accessed March 13, 2023.

[542] Ibid.

excluded from the measure.[543] Thus, this measure does not include beneficiaries with the following conditions: adrenal mass, hematuria, infections of kidney, jaundice, liver lesion (mass or neoplasm), malignant neoplasm of bladder, malignant neoplasm of pancreas, diseases of urinary system, pancreatic disorders, non-traumatic aortic disease, and unspecified disorder of kidney or ureter.[544]

We invite public comment on this proposal.

b. Proposal To Adopt the Median Time From Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients Measure

(1) Background

Care provided in the ED will likely be a focus of REH services and we seek measures that assess the quality of care in this setting. Improving ED throughput times is important for alleviating overcrowding and reducing wait times.[545] Crowding has led to a number of potentially avoidable problems in EDs, including ambulance diversion, prolonged patient waiting times, and potentially poor patient outcomes due to delays, such as in the administration of medication.[546]

The Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (the Median Time for Discharged ED Patients measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2013 payment determination (75 FR 72086).

(2) Measure Overview

The Median Time for Discharged ED Patients measure is a chart-abstracted measure that evaluates the time between the arrival to and departure from the ED, also known as ED throughput time.

As described in the measure specifications and Measure Information Form (MIF),[547] [548] measure data are stratified for four separate calculations: (1) the Overall Rate is calculated as the overall rate; (2) the Reported Measure calculates data for all patients excluding psychiatric/mental health patients and transfer patients; (3) Psychiatric/Mental Health calculates data for psychiatric/mental health patients; and (4) Transfers calculates data for transfer patients.

Although section 1861(kkk)(7)(c)(i) of the Act requires that measures specified by the Secretary for use in CMS hospital quality programs be endorsed by the entity with a contract under section 1890(a) of the Act, section 1861(kkk)(7)(C)(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. This measure is not CBE-endorsed. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception in section 1861(kkk)(7)(C)(ii) of the Act applies for this measure.

The Median Time for Discharged ED Patients measure was included in the 2022 MUC list.[549] In its February 1, 2023 Final Recommendations, the MAP stated their belief that changes in wait times may not directly influence mortality or patient outcomes and had concerns that transfer times may be delayed due to weather and transport safety issues that are out of a facility's control. The Rural Health Advisory Group expressed similar concerns regarding the impact on transport times of issues beyond a facility's control, such as weather, local facility transport modalities, and distance; but also noted that transfer time for trauma patients is especially important. The Health Equity Advisory Group, however, emphasized the importance of the measure and its potential to advance health equity. Ultimately, the MAP did not provide support for this measure for the REHQR Program.[550]

We recognize the concerns expressed in the MAP Final Recommendation. However, we believe that ED wait times have significant impact on patients. Prolonged waiting times are associated with worse patient experience in patients discharged from the emergency department.[551] Studies demonstrate that higher patient satisfaction is associated with patient outcomes, including decreased mortality [552] and lower readmission rates.[553]

We acknowledge that transfer times may be delayed due to weather and transport safety issues that are out of a facility's control. However, we believe that some factors such as building transfer relationships and process improvements can be addressed by hospitals to improve ED wait times. Further, this information could be useful to Medicare beneficiaries and other interested parties toward assessing care provided and the care environment of a hospital. By implementing this measure, we are supporting CMS National Quality Strategy goals, including embedding quality into the care journey (for example, by addressing quality throughout the patient experience); promoting safety (for example, by minimizing associated negative patient outcomes, such as delayed administration of medications); and increasing alignment (given that this measure is used in other quality programs).[554] Alignment of measures across CMS federal programs is also an

[543] American College of Radiology. ACR Appropriateness Criteria. Available at: *https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria*. Last accessed April 4, 2023.

[544] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Abdomen Computed Tomography (CT)—Use of Contrast Material. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=1842&sectionNumber=1*. Last accessed April 3, 2023.

[545] Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open*, 1(5):1052–1059. doi: 10.1002/emp2.12100.

[546] Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst*. 2021; 5(2). *https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217*. Last accessed February 28, 2023.

[547] A Measure Information Form provides detail on the rationale for a measure as well as the relevant numerator statements, denominator statements and measure calculations.

[548] Hospital OQR Program ED Throughput Measures Information Form. Available at: *https://qualitynet.cms.gov/files/638e75e376962e0016ad907d?filename=1d_ED_Throughput_set_v16.0a.pdf* (p. 1–26). Last accessed February 28, 2023.

[549] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet*. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*. Last accessed March 13, 2023.

[550] Centers for Medicare & Medicaid Services. *2022–2023 MAP Final Recommendations*. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*. Last accessed March 13, 2023.

[551] Nyce, A, Gandhi, S, Freeze, B, Bosire, J, Ricca, T, Kupersmith, E, Mazzarelli, A, Rachoin, J–S. Association of Emergency Department Waiting Times With Patient Experience in Admitted and Discharged Patients. 2021. J Pat Exp 8:1–7. *https://doi.org/10.1177/23743735211011404*.

[552] Glickman SW, Boulding W, Manary M, Staelin R, Roe MT, Wolosin RJ. et al. Patient satisfaction and its relationship with clinical quality and inpatient mortality in acute myocardial infarction. *Circ Cardiovasc Qual Outcomes*. 2010; 3:188–95. Available at *https://www.ahajournals.org/doi/10.1161/CIRCOUTCOMES.109.900597?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200pubmed*.

[553] Boulding W, Glickman SW, Manary MP, Schulman KA, Staelin R. Relationship between patient satisfaction with inpatient care and hospital readmission within 30 days. *Am J Manag Care*. 2011;17:41–8. Available at *https://www.ajmc.com/view/ajmc_11jan_boulding_41to48*.

[554] CMS (2023). What is the CMS National Quality Strategy? Available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. Last accessed April 13, 2023.

objective of the Meaningful Measures 2.0 initiative.[555] This measure also promotes the Meaningful Measures goal of driving outcome improvement through public reporting, given that CMS predicts that data for this measure will be reported in sufficient numbers to permit public reporting (see Table 79 in section XVI.B.1 of this proposed rule).

Care Compare data current to January 2023 show that CAHs and subsection (d) hospitals with fewer than 50 beds reported sufficient data for this measure under the Hospital OQR Program to be publicly reported for all of these strata, indicating that hospitals eligible to convert to REH status would be able to report data for this measure to a level sufficient for public reporting. Our proposal to publicly report these data is further described in section XVI.B.8.c of this proposed rule. Thus, we propose to adopt this measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

The measure would be calculated using chart-abstracted data on a rolling quarterly basis, and would be publicly reported in aggregate for one calendar year. Sources of the relevant data may include claims forms, electronic health care data, electronic health records (EHRs), or paper records. Data elements necessary for the calculation of the measure include arrival time, discharge code, Evaluation and Management (E/M) code, ED departure date, ED departure time, ICD–10–CM principal diagnosis code, and outpatient encounter date.

(4) Measure Calculation

The measure calculates the median time (in minutes) from ED arrival to time of departure from the ED for patients discharged from the ED. Reducing the time patients remain in the ED can improve access to treatment and increase quality of care.[556] [557] Improvement is noted as a decrease in the median value. The included population is any ED patient who completes an ED discharge process. This process measure is not risk-adjusted or risk-stratified.[558] However, the measure is stratified by certain subgroups of patients, as described in the next section.

(5) Cohort

The Median Time for Discharged ED Patients measure is calculated in stratified subsections for certain types of patients: (1) Median Time from ED Arrival to ED Departure for Discharged ED Patients—Reported Measure, which excludes psychiatric/mental health and transferred patients; (2) Median Time from ED Arrival to ED Departure for Discharged ED Patients—Psychiatric/Mental Health Patients, which includes information only for psychiatric/mental health patients; (3) Median Time from ED Arrival to ED Departure for Discharged ED Patients—Transfer Patients, which includes information only for patients transferred from the ED; and (4) Median Time from ED Arrival to ED Departure for Discharged ED Patients—Overall Rate. The measure excludes patients who expired in the ED, left against medical advice, or whose discharge was not documented or unable to be determined.[559]

We invite public comment on this proposal.

c. Proposal To Adopt the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy Measure

(1) Background

Colonoscopies are one of the most frequently performed procedures in the outpatient setting in the United States,[560] with more than 16 million procedures performed each year.[561] Colonoscopies are associated with a range of well-described and potentially preventable adverse events that can lead to hospital visits, repeat procedures, or surgical intervention for treatment, including colonic perforation, gastrointestinal (GI) bleeding, and abdominal pain.[562] While hospital visits are generally unexpected after an outpatient colonoscopy, the literature indicates that the majority of such visits occurring later than seven days post-procedure are more likely to be unrelated to the procedure.[563] Such hospital visits occurring later than seven days post-procedure may be complicated by patient comorbidities and high risk factors.[564]

As noted in Table 79 with Hospital OQR Program data current to 2023, the average rate of reported unplanned hospital visits per 1,000 colonoscopies at CAHs and rural subsection (d) hospitals eligible for REH conversion are 14.3 (1.43 percent) and 14.4 (1.44 percent), respectively. These average rates are in line with those of small, urban subsection (d) hospitals, and larger, rural hospitals subsection (d) with 50 or more beds (that is, with categories of subsection (d) hospitals that are not eligible for REH conversion). Hospitals in these categories that are in the top 10th percentile in terms of numbers of cases (that is, unplanned hospital visits within 7 days of an outpatient colonoscopy) reported, however, do appear to perform differently. In this percentile, hospitals eligible for REH conversion do not perform as well as those that are not eligible for REH conversion. REH-eligible hospitals with these larger caseloads have a higher rate of unplanned hospital visits per 1,000 colonoscopies than non-REH eligible hospitals.

The Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy (the 7-Day Hospital Visit Rate After Outpatient Colonoscopy) measure was adopted for reporting in the Hospital OQR Program in 2015, first with a dry run (that is, confidential reports containing measure results were made available for hospitals to review, provide feedback, and become familiar with the measure methodology in advance of public reporting and impact on payment determinations), and then fully implemented beginning with the

[555] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*. Last accessed April 13, 2023.

[556] Smalley, CM, Simon, EL, Meldon, SW, et al. (2020). The impact of hospital boarding on the emergency department waiting room. *JACEP Open*, 1(5):1052–1059. doi: 10.1002/emp2.12100.

[557] Kelen GD, Wolfe R, D-Onofrio G, Mills AM, Diercks D, Stern SA, Wadman MC, Sokolove PE. Emergency Department Crowding: The Canary in the Health Care System. *NEJM Catalyst*. 2021; 5(2). *https://catalyst.nejm.org/doi/full/10.1056/CAT.21.0217*.

[558] CMIT. Median time from ED Arrival to ED Departure for Discharged ED patients. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=695&sectionNumber=1*. Last accessed April 4, 2023.

[559] QualityNet. Hospital Outpatient Specifications Manuals. Available at: *https://qualitynet.cms.gov/outpatient/specifications-manuals*. Last accessed April 5, 2023.

[560] Definitive Healthcare. Top 10 Outpatient Procedures at Surgery Centers and Hospitals. Available at: *https://www.definitivehc.com/blog/top-10-outpatient-procedures-at-ascs-and-hospitals#:~:text=Definitive%20Healthcare%20data%20shows%20that,procedures%20at%20ASCs%20by%20volume*. Last accessed March 12, 2023.

[561] I Data Research. An Astounding 16.6 Million Colonoscopies are Performed Annually in The United States. (*https://idataresearch.com/an-astounding-19-million-colonoscopies-are-performed-annually-in-the-united-states/*[sic]). Accessed February 28, 2023.

[562] I. Ranasinghe, C.S. Parzynski, R. Searfoss, et al. Differences in colonoscopy quality among facilities: development of a post-colonoscopy risk-standardized rate of unplanned hospital visits. Gastroenterology, 150 (2016), pp. 103–113 Available at: *https://www.gastrojournal.org/action/showPdf?pii=S0016-5085%2815%2901353-0*. Last accessed March 12, 2023.

[563] L.B. Grossberg, A. Vodonos, K. Papamichael, et al. Predictors of post-colonoscopy emergency department use. Gastrointest Endosc, 87 (2018), pp. 517–525. Available at: *https://www.sciencedirect.com/science/article/pii/S0016510717322010?viewFullText=true#sec4*. Last accessed March 12, 2023.

[564] Ibid.

CY 2018 payment determination (79 FR 66948 through 66955).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure was on the 2022 MUC list.[565] In its February 1, 2023 Final Recommendations, the MAP considered and supported it for rulemaking for the REHQR Program given that a previous version of this measure specified for colonoscopies performed in ambulatory surgical centers (ASCs) and hospital outpatient departments (HOPDs) received endorsement from the CBE (CBE #2539) in 2014 and 2020, and that this measure is currently in use in the ASCQR and Hospital OQR Programs.[566]

As evidenced in Table 79, CAHs and small, rural subsection (d) hospitals—hospitals which are eligible to convert to REH status—performed a sufficient number of colonoscopies and had sufficient measure data for this measure to be publicly reported on the Care Compare site. Using data current to January 2023 for the Hospital OQR Program, out of those eligible to report data, 65.5 percent (131) of small, rural subsection (d) hospitals and 44.7 percent (609) of CAHs eligible to convert to REHs reported for this measure.

We believe this could be an important measure for those REHs that elect to provide outpatient services and for patients seeking information regarding complications following this procedure. Inclusion of this measure in the REHQR Program will also promote goals of the CMS National Quality Strategy, including embedding quality into the care journey; advancing health equity within and across settings; and increasing alignment of performance metrics, programs, policy, and payment across CMS.[567] Inclusion will also advance goals of the Meaningful Measures 2.0 initiative, including by empowering consumers to make good health care choices by providing public transparency; and by leveraging quality measures to promote health equity and close gaps in care.[568] Therefore, we propose to include the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

This outcome measure is calculated using Medicare FFS claims and enrollment data, estimating a facility-level rate of risk-standardized, all-cause, unplanned hospital visits within 7 days of an outpatient colonoscopy among Medicare FFS patients aged 65 years and older.[569] In alignment with the reporting period for this measure as used in the Hospital OQR Program, the initial reporting period is a three-year period beginning with patient encounters from January 1, 2024 through December 31, 2026 with annual updates on a rolling basis.[570]

(4) Measure Calculation

The measure defines the outcome as any (one or more) unplanned hospital visits within 7 days of an outpatient colonoscopy procedure.[571] For this measure, a hospital visit includes any ED visit, observation stay, or unplanned inpatient admission to any short-term, acute care facility.[572] [573] The measure score is the ratio of predicted hospital visits (numerator) over the expected hospital visits (denominator) multiplied by the national observed rate. The numerator is the number of predicted (meaning adjusted actual) hospital visits, which is the number of unplanned hospital visits the facility is predicted to have within 7 days of colonoscopy, and it accounts for the observed unplanned hospital visit rate, the number of colonoscopies performed at the facility, and the facility's case mix. The denominator is the number of expected hospital visits, which is the number of unplanned hospital visits the facility is expected to have based on the facility's case mix. It is the sum of all patients' expected probabilities of a hospital visit, given their risk factors and the risk of readmission at an average facility. The national observed rate is the national unadjusted number of patients who had a hospital visit post-colonoscopy among all patients who had a colonoscopy.[574] Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

We note that the measure calculation is comparable to the Hospital OQR Program version of the measure, as set out in the CY 2015 OPPS/ASC final rule (79 FR 66948 through 66955).

(5) Cohort

The measure denominator includes Medicare patients with paid, final action claims for typical colonoscopies. The denominator excludes patients undergoing concomitant high-risk upper GI endoscopy because this is a more extensive procedure that places these patients at a higher risk for hospital visits than patients undergoing a typical colonoscopy, as well as patients with a history of inflammatory bowel disease (IBD) or diverticulitis in the year preceding the colonoscopy because we likely could not fully characterize and adjust for their pre-procedure risk of needing a post-procedure hospital visit or identify whether these admissions are planned or unplanned. The measure also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the month after the procedure to ensure all patients have complete data available for outcome assessment. For further discussion of the cohort for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, please see ''2022 Measure Updates and Specifications

[565] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[566] Centers for Medicare & Medicaid Services. *2022–2023 MAP Final Recommendations.* Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.* Last accessed March 13, 2023.

[567] CMS (2023). What is the CMS National Quality Strategy? *Available at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.* Last accessed April 13, 2023.

[568] CMS (2022), Meaningful Measures 2.0: Moving from Measures Reduction to Modernization. Available at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.* Last accessed April 13, 2023.

[569] CMIT. Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://cmit.cms.gov/cmit/#/MeasureView?variantId=1354&sectionNumber=1.* Last accessed February 28, 2023.

[570] CMS, Hospital Outpatient Specifications Manuals—Measure Information Form, 1.6 Outcome Measures, OP–32: Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy. Available at *https://qualitynet.cms.gov/files/638e788ffb845c00175c7aaf?filename=1u_OP32MIF_v16.0a.pdf.* Last accessed February 28, 2023.

[571] 2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program. available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.* Last accessed May 2, 2023.

[572] Ibid.

[573] CMS, Frequently Asked Questions. Available at: *https://qualitynet.cms.gov/outpatient/measures/colonoscopy/resources.* Last accessed May 2, 2023.

[574] ''Included colonoscopies'' are outpatient colonoscopy procedures using Healthcare Common Procedure Coding System (HCPCS) codes G0121 and G0105, and Common Procedural Terminology (CPT) codes 45378, 45380, 45385, 45384, 45383, and 45381. This measure also uses a number of exclusion criteria. Additional methodology details and information obtained from public comments for measure development are available at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html* under ''Hospital Outpatient Colonoscopy.''

Report: Hospital Outpatient Quality Reporting Program,'' available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology*.

(6) Risk Adjustment

The statistical risk-adjustment model includes 15 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within seven days following colonoscopy. Additional methodology details and information for measure development are available at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology*.

We invite public comment on this proposal.

d. Proposal To Adopt the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery Measure

(1) Background

Most surgical procedures in the United States are performed in outpatient settings; there are approximately 23 million such procedures performed annually.[575] Same-day surgery offers significant patient benefits as compared with inpatient surgery, including shorter waiting times, avoidance of hospitalizations, and rapid return home.[576] Furthermore, as same-day surgery costs are significantly less than an equivalent inpatient surgery, there is a significant cost saving opportunity to the health system.[577] With the ongoing shift towards outpatient surgery, assessing the quality of surgical care provided by hospitals has become increasingly important. Patients undergoing same-day surgery may require subsequent unplanned hospital visits for a broad range of reasons. While most outpatient surgery is safe, there are well-described and potentially preventable adverse events that occur after outpatient surgery, such as uncontrolled pain, urinary retention, infection, bleeding, and venous thromboembolism, which can result in unplanned hospital visits.[578] Similarly, direct admissions after surgery that are primarily caused by nonclinical patient considerations (for example, lack of transport home upon discharge) or facility logistical issues (for example delayed start of surgery) are common causes of unplanned yet preventable hospital admissions following same-day surgery.[579] Hospital utilization following same-day surgery is an important and accepted patient-centered outcome reported in the literature. As evidenced by one study, ''national estimates of hospital visit rates following surgery vary from 0.5 to 9.0 percent based on the type of surgery, outcome measured (admissions alone or admissions and ED visits), and timeframe for measurement after surgery,'' [580] suggesting variation in surgical and discharge care quality. However, providers (hospitals and surgeons) are often unaware of their patients' hospital visits after surgery because patients often present to the ED or to different hospitals.[581] This risk-standardized measure provides the opportunity for providers to improve the quality of care and to lower the rate of preventable adverse events that occur after outpatient surgery.

The Risk-Standardized Hospitalized Visits Within 7 Days After Hospital Outpatient Surgery (the 7-Day Hospital Visit Rate After Outpatient Surgery) measure was adopted for reporting in the Hospital OQR Program beginning with the CY 2020 payment determination (81 FR 79771).

(2) Measure Overview

The 7-Day Hospital Visit Rate After Outpatient Surgery measure would make unplanned patient hospital visits (ED visits, observation stays, or unplanned inpatient admissions) after surgery more visible to providers and patients through publicly reporting scores. It could also encourage providers to engage in quality improvement activities to reduce these visits by providing feedback to facilities and physicians. This measure meets the National Quality Strategy goals of embedding quality into the care journey and promoting safety.[582] We expect that the measure would promote improvement in patient care over time.

The 7-Day Hospital Visit Rate After Outpatient Surgery measure was on the 2022 MUC list.[583] The Rural Health Advisory Group members did not have any rural health concerns about the measure. We believe that this proposed measure reflects consensus among the affected parties as public comment received during the MAP and measure development processes was in agreement with the MAP's conclusions on the measure. The CBE recommended the measure for rulemaking (CBE #2687).[584]

We believe it is important to reduce adverse patient outcomes associated with preparation for surgery, the procedure itself, and follow-up care. Therefore, we propose to include the 7-Day Hospital Visit Rate After Outpatient Surgery measure in the REHQR Program beginning with the CY 2024 reporting period.

(3) Data Sources

The proposed 7-Day Hospital Visit Rate After Outpatient Surgery measure would be calculated from Part A and Part B Medicare administrative claims data for Medicare FFS beneficiaries with an outpatient same-day surgical procedure excluding eye surgeries and colonoscopies (except colonoscopy with biopsy). Colonoscopies are excluded from this measure as these procedures are examined separately on their own. The exclusion of eye procedures is discussed below. The performance period for the measure is one year (that is, the measure calculation includes eligible outpatient same-day surgeries occurring within a 1-year timeframe),[585] and would begin with the CY 2024 reporting period. We also considered increasing the data collection time period, to account for low volume, to 2 or 3 years.

[575] Munnich, EL, & Richards, MR. (February, 2022). Long-run growth of ambulatory surgery centers 1990–2015 and Medicare payment policy. *Health Services Research, 57*(1), 66–71. *https://doi.org/10.1111/1475-6773.13707*.

[576] Banner Health. Outpatient Experience & Benefits. Available at: *https://www.bannerhealth.com/services/outpatient-surgery/experience-benefits*. Last accessed April 4, 2023.

[577] Munnich, EL, & Parente, ST. (January, 2018). Returns to specialization: Evidence from the outpatient surgery market. Journal of health economics, 57, 147–167. *https://doi.org/10.1016/j.jhealeco.2017.11.004*.

[578] Bongiovanni, T, Parzynski, C, Ranasinghe, I, Steinman, MA, & Ross, JS. (July 2021). Unplanned hospital visits after ambulatory surgical care. *PloS one, 16*(7), e0254039. *https://doi.org/10.1371/journal.pone.0254039*.

[579] Ibid.

[580] Ibid.

[581] Williams, BR, Smith, LC, Only, AJ., Parikh, HR, Swiontkowski, MF, & Cunningham, BP. (September, 2021). Unplanned Emergency and Urgent Care Visits After Outpatient Orthopaedic Surgery. *Journal of the American Academy of Orthopaedic Surgeons. Global research & reviews, 5*(9), e21.00209. *https://doi.org/10.5435/JAAOSGlobal-D-21-00209*.

[582] CMS, What is the CMS National Quality Strategy? Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[583] Centers for Medicare & Medicaid Services. *2022 Measures Under Consideration Spreadsheet*. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*. Last accessed March 13, 2023.

[584] Centers for Medicare & Medicaid Services. *MAP 2016 Considerations for Implementing Measures in Federal Programs—Hospitals*. Available at: *https://www.qualityforum.org/Publications/2016/02/MAP_2016_Considerations_for_Implementing_Measures_in_Federal_Programs_-_Hospitals.aspx*. Last accessed March 13, 2023.

[585] QualityNet. 2022 Measure Updates and Specifications Report (2022), available at *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology*. Last accessed February 28, 2023.

(4) Measure Calculation

The measure outcome includes unplanned hospital visits within seven days after a surgery performed at an REH that are: (1) an inpatient admission at a separate hospital that can admit patients; or (2) an ED visit or observation stay at the REH or other hospital occurring after discharge. If more than one unplanned hospital visit occurs, only the first hospital visit within the outcome timeframe is counted in the outcome.

The facility-level measure score is a ratio of the predicted to expected number of post-surgical hospital visits among the hospital's patients. The numerator of the ratio is the number of hospital visits predicted for the hospital's patients accounting for its observed rate, the number of surgeries performed at the hospital, the case-mix, and the surgical procedure mix. The denominator of the ratio is the expected number of hospital visits given the hospital's case-mix and surgical procedure mix. A ratio of less than one indicates the hospital's patients have fewer post-surgical visits than expected compared to hospitals with similar surgical procedures and patients; and a ratio of greater than one indicates the hospital's patients were estimated as having more visits than expected.

To ensure the accuracy of the algorithm for attributing claims data and the comprehensive capture of hospital surgeries potentially affected by the CMS 3-day payment window policy,[586] we identify physician claims for same-day surgeries in hospital settings from the Medicare Part B Standard Analytical Files (SAF) with inpatient admissions that occur within 3 days after these surgeries that lack a corresponding hospital facility claim. Under the 3-day payment window policy, all outpatient diagnostic services furnished to a Medicare beneficiary by a hospital (or an entity wholly owned or operated by the hospital), on the date of a beneficiary's admission or during the 3 days immediately preceding the date of a beneficiary's inpatient hospital admission, must be included on the Part A bill for the beneficiary's inpatient stay at the hospital. Hospitals must include the following information on the claim for a beneficiary's inpatient stay: (1) the diagnoses; (2) procedures; and (3) charges for all outpatient diagnostic services and admission-related outpatient nondiagnostic services that are furnished to the beneficiary during the 3-day payment window.[587] A surgery identified as affected by this policy would be attributed to the appropriate hospital facility using the facility provider identification from the inpatient claim.[588]

(5) Cohort

The measure includes Medicare FFS patients aged 65 years and older undergoing same-day, outpatient surgery in REHs, excluding eye surgeries and colonoscopies, but including colonoscopy with biopsy.

''Same-day surgeries'' are substantive surgeries and procedures listed on Medicare's list of covered ASC procedures excluding eye surgeries and colonoscopies (except colonoscopy with biopsy).[589] This list was developed for Medicare to identify surgeries that can be safely performed as same-day surgeries and do not typically require an overnight stay. Surgeries on the ASC list of covered procedures do not involve or require major or prolonged invasion of body cavities, extensive blood loss, major blood vessels, or care that is either emergent or life-threatening.

Although Medicare developed this list of surgeries for ASCs, we use it more broadly for this measure for two reasons. First, it aligns with our target cohort of surgeries that have low to moderate risk profile and are safe to be performed as same-day surgeries. By only including surgeries on this list in the measure, we effectively do not include surgeries performed at hospitals that typically require an overnight stay which are more complex, higher risk surgeries. Second, we use this list of surgeries because it is annually reviewed and updated by Medicare, and includes a transparent public comment submission and review process for addition or removal of procedures codes. To view the ASC covered procedures list for 2023, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.* On that page, readers may select ''CMS–1772–FC'' from the list of regulations. The ASC Addenda are contained in a zipped folder entitled ''Addendum AA, BB, DD1, DD2, and EE.'' Addendum AA includes the relevant list of covered surgeries.

For further discussion of the cohort for this measure, please see ''2022 Measure Updates and Specifications Report: Hospital Outpatient Quality Reporting Program,'' available at *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

The cohort for this measure excludes eye surgeries. Eye surgery is performed in high volume and is generally perceived as being ''low risk.'' However, studies have indicated non-insignificant levels of hospital visits following cataract surgery. One study reported 0.3 percent of patients as having an inpatient admission within 7 days following cataract surgery[590] and another study showing a 1.77 percent of patients with ED visits within 30 days following cataract surgery.[591] The measure cohort also excludes procedures for patients who lack continuous enrollment in Medicare FFS Parts A and B in the seven days after the procedure to ensure all patients have complete data available for outcome assessment.

(6) Risk Adjustment

The statistical risk-adjustment model includes 25 clinically relevant risk-adjustment variables that are strongly associated with risk of hospital visits within 7 days following outpatient surgery.[592] The measure risk-adjusts for surgical procedure complexity using two variables. First, it adjusts for surgical procedure complexity using the

[586] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window.* Accessed May 4, 2023.

[587] Three Day Payment Window Implementation of New Statutory Provision Pertaining to Medicare 3-Day (1-Day) Payment Window Policy—Outpatient Services Treated As Inpatient. Centers for Medicare and Medicaid Services (CMS). Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Three_Day_Payment_Window.* Last accessed on March 28, 2023.

[588] For additional methodology details, we refer readers to the documents posted at: *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*, including ''2016 Measure Updates and Specifications Report: Hospital Visits after Hospital Outpatient Surgery Measure (PDF)''. Last accessed March 21, 2023.

[589] YNHHSC/CORE (2016). 2016 Measure Updates and Specifications Report Hospital Outpatient Quality Reporting Program 2022. Available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.* Last accessed March 21, 2023.

[590] Wang, SY, Blachley, TS, Andrews, CA, Avanian, JZ, Lee, PP, & Stein, JD. Feb 22, 2016). Hospitalization after Cataract Surgery in a Nationwide Managed-Care Population. PLOS ONE (11:2). *https://doi.org/10.1371/journal.pone.0149819.*

[591] Sahil Aggarwal, Andrew Gross, Alex Snyder, Jay Rathinavelu, Terry Kim, Leon Herndon. Younger Age and Longer Case Times Associated With Emergency Department Visits After Cataract Surgery Published: August 23, 2022DOI: *https://doi.org/10.1016/j.ajo.2022.08.017.*

[592] Information about the risk-adjustment model and measure methodology are located in the Measure Updates and Specifications Report available on QualityNet at: *https://qualitynet.cms.gov/outpatient/measures/surgery/methodology.*

Work Relative Value Units (RVUs).[593] Work RVUs are assigned to each CPT procedure code and approximate procedure complexity by incorporating elements of physician time and effort. Second, it classifies each surgery into an anatomical body system group using the Agency for Healthcare Research and Quality (AHRQ) Clinical Classification System (CCS),[594] to account for organ-specific differences in risk and complications, which are not adequately captured by the Work RVU alone.

We invite public comment on this proposal.

6. Summary of Proposed REHQR Program Measure Set Beginning With the CY 2024 Reporting Period

Table 80 summarizes the proposed REHQR Program measure set beginning with the CY 2024 reporting period:

TABLE 80: Proposed REHQR Program Measure Set Beginning With the CY 2024 Reporting Period

CBE #	Measure Name
None	Abdomen Computed Tomography (CT) – Use of Contrast Material
None	Median Time from ED Arrival to ED Departure for Discharged ED Patients
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy*
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery

*Reporting period for this measure is a three-year period, beginning CYs 2024-2026.

TABLE 81: Urban Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE/Hardship	Percent with ECE/Hardship	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Urban	3,088	95.1%	98	3.0%	60	1.8%	3,246
Bed Size Urban							
0-50	667	87.0%	81	10.6%	19	2.5%	767
51-100	408	96.5%	6	1.4%	9	2.1%	423
101+	2,013	97.9%	11	0.5%	32	1.6%	2,056
Provider Urban							
CAH	402	85.7%	67	14.3%	0	0.0%	469
IQR-Eligible	2,643	96.8%	26	1.0%	60	2.2%	2,729
Voluntary**	43	89.6%	5	10.4%	0	0.0%	48

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be noncompliant with the requirements of a quality reporting program, but they can request a Hardship Exception through the PI Program. Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit CY 2021 eCQM measures for FY 2023.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

[593] Coberly, S. (January 12, 2015). The Basics; Relative Value Units (RVUs). National Health Policy Forum. Available at: *https://hsrc.himmelfarb.gwu.edu/cgi/viewcontent.cgi?article=1275&context=sphhs_centers_nhpf*. Last accessed February 28, 2023.

[594] HCUP Clinical Classifications Software for Services and Procedures. Healthcare Cost and Utilization Project (HCUP). 2008. Agency for Healthcare Research and Quality. Available at: *https://www.hcup-us.ahrq.gov/toolssoftware/ccs_svcsproc/ccssvcproc.jsp*. Last accessed February 28, 2023.

7. REHQR Program Measures and Topics for Future Consideration

a. Request for Comment: Electronic Clinical Quality Measures (eCQMs) for Reporting Quality Data Under the REHQR Program

eCQMs are measures specified in a standard electronic format that use data electronically extracted from EHRs and/or health information technology systems to measure the quality of health care provided. Through electronic reporting, hospitals have leveraged EHRs to capture, calculate, and electronically submit quality data instead of manually chart-abstracting and submitting to CMS. Adoption of certain eCQMs into the REHQR Program could address high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.[595]

We acknowledge that technological, monetary, and staffing barriers may present challenges to eCQM adoption and use at some REHs. Although some REH staff may have had experience reporting eCQMs in the Hospital IQR, Hospital OQR, or Medicare Promoting Interoperability (PI) Programs during the time period when their REHs were organized as CAHs or subsection (d) hospitals, we acknowledge that challenges will remain. We see evidence of these challenges when analyzing eCQM reporting under the Medicare PI Program for eligible hospitals and CAHs. Tables 81 and 82 compare urban and rural hospital eCQM reporting, as defined by census area, with respect to the Medicare PI Program for CY 2021. Most hospitals of all bed sizes successfully reported eCQMs, but eCQM submission compliance percentages for smaller hospitals and rural hospitals were slightly lower than for larger or urban hospitals.

BILLING CODE 4120–01–P

TABLE 82: Rural Hospitals that did or did not meet CY 2021 Reporting Period Promoting Interoperability eCQM Submission Requirements or were granted an Extraordinary Circumstances Exception (ECE)/Hardship Exception*

Hospital Type and Location	MET	Percent Met	NOT MET	Percent Not Met	ECE	Percent with ECE	Total
Rural and Urban Hospitals Eligible to submit eCQMs for CY 2021 Reporting Period	4,123	92.0%	286	6.4%	71	1.6%	4,480
Location							
Rural	1,035	83.9%	188	15.2%	11	0.9%	1,234
Bed Size Rural							
0-50	768	81.1%	170	18.0%	9	1.0%	947
51-100	122	93.1%	7	5.3%	2	1.5%	131
101+	145	92.9%	11	7.1%	0	0.0%	156
Provider Rural							
CAH	672	80.2%	166	19.8%	0	0.0%	838
IQR-Eligible	327	95.1%	6	1.7%	11	3.2%	344
Voluntary**	36	69.2%	16	30.8%	0	0.0%	52

*A CAH cannot request an extraordinary circumstances exception (ECE) if it is found to be noncompliant with the requirements of a quality reporting program, but they can request a Hardship Exception through the PI Program. Data source: Hospitals are identified from eCQM data submitted via Hospital Quality Reporting for FY 2023 and PRS accessed May 18, 2022. Hospitals are included if they were eligible to submit CY 2021 eCQM measures for FY 2023.

**Voluntary hospitals are those not required to participate in the Hospital IQR Program (located in Puerto Rico and other U.S. Territories and Maryland) as well as seven cancer centers or research hospitals that choose to report.

BILLING CODE 4120–01–C

We believe that certain eCQMs, if adopted into the REHQR Program, could provide insightful quality measure data for monitoring REHs and potentially lower provider burden. For example, the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults eCQM (the Excessive Radiation eCQM) could be adopted into the REHQR Program to improve patient outcomes and patient safety. This eCQM provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. The measure is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate

[595] CMS. Meaningful Measures Initiative. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy. Last accessed April 3, 2023.

image quality, relative to evidence-based thresholds based on the clinical indication for the exam.[596] This measure is not risk-adjusted. The purpose of this measure is to reduce unintentional harm to patients and provide REHs with a reliable method to assess harm reduction efforts and modify their improvement efforts. We propose adoption of the Excessive Radiation eCQM for the Hospital OQR Program. We refer readers to section XIV.B.3.c of this proposed rule for a discussion of the Hospital OQR Program proposal.

We also refer readers to section XIV of the CY 2022 OPPS/ASC proposed rule (86 FR 42232 through 42237) where we requested information on potential actions and priority areas that would enable the continued transformation of our quality measurement enterprise toward greater digital capture of data and use of the Fast Healthcare Interoperability Resources (FHIR) standard. This will be taken into consideration in future years when deciding how and when to introduce eCQMs to the REHQR Program.

We invite public comment on the use of eCQMs in the REHQR Program, any specific eCQM measures that we should consider for inclusion in the REHQR Program measure set, including the Excessive Radiation eCQM, and any considerations or criteria we should use in identifying eCQM measures to propose for future inclusion.

b. Request for Comment: Care Coordination Measures

As part of future rulemaking, we may consider adding measures to the REHQR Program measure set that are relevant to the coordination of care between REHs and other kinds of healthcare providers. REHs encounter challenges in coordinating care that are specific to rural settings. Geographically isolated areas typically have fewer healthcare settings and providers, and experience difficulties related to workforce shortages, transportation issues, and lack of information technology capabilities, such as the availability of broadband networks.[597] Other challenges relate to shifting workforce availability (for example, issues related to the availability of traveling nurses or independent healthcare providers) and limited access to specialists, diagnostic equipment, and other resources.[598] In particular, REHs are required to have in effect a transfer agreement with a level I or level II trauma center,[599] such that patients that present at an REH with needs for longer-term inpatient care may receive that care. REHs must, therefore, address issues related to the coordination of care for transferred patients.

We have sought to identify measures relevant to care coordination in rural settings that are also important, impactful, reliable, accurate, and clinically relevant. In the CY 2023 OPPS/ASC final rule, we provided responses to the comments received on our request for information on additional topics for quality measures appropriate for the REH setting (87 FR 72146 through 72149). Many of these comments addressed the provision of telehealth, an issue that impacts care coordination (87 FR 72146 through 72147). The CBE provided additional information on this topic in 2021, when they identified a list of 324 measures relevant to the provision of telehealth.[600] We believe that a number of these measures are directly related to the coordination of care, such as measures CBE #0006 Care Coordination, CBE #0097 Medication Reconciliation Post-Discharge, and CBE #0326 Advance Care Plan.[601] The current Medicare Beneficiary Quality Improvement Project (MBQIP) measures also include several ''care transitions'' measures that may be relevant to the coordination of care for REHs. Relevant MBQIP measures include Emergency Department Transfer Communication (on which we invited public comment in the CY 2022 OPPS/ASC proposed rule, at 86 FR 42285 through 42289), Discharge Planning, and Medication Reconciliation.[602]

We invite public comment on the use of care coordination measures including telehealth measures in the REHQR Program, any specific measures that we should consider for inclusion in the REHQR Program measure set regarding care coordination, and any considerations or criteria we should use in determining which if any coordination of care measures to propose for future inclusion.

c. Request for Comment: Tiered Approach Framework

We refer readers to section XVII of the CY 2022 OPPS/ASC proposed rule, where we included a request for information (RFI) on REHs (86 FR 42285 through 42289). We received more than 50 comments in response to the RFI, including one suggestion to implement a multi-tiered approach for quality measures and reporting requirements to incentivize REH reporting.

Within such a tiered framework, Tier 1 could encompass a set of measures that would be required for all REHs and would focus on measures applicable for the required ED and observation services at REHs. Tier 2 could apply only to REHs that choose to provide additional outpatient services; the measures in that set would be related to the optional services provided.

Measures being proposed in this proposed rule for adoption into the REHQR Program measure set are the: (1) Abdomen CT measure, (2) Median Time for Discharged ED Patients measure, (3) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (4) 7-Day Hospital Visit Rate After Outpatient Surgery measure. Two of these proposed measures are related to services that REHs must provide to participate in the Medicare program. The other two proposed measures are related to services that could be furnished on an outpatient basis at the election of the REH.[603] To fit into an example scenario of a tiered approach, Tier 1 could include the measures related to required services, which are the diagnostic, claims-based Abdomen CT measure, and the chart-abstracted Median Time for Discharged ED Patients measure. Tier 2 could consist of the measures related to services the REH may elect to provide, which are the claims-based 7-Day Hospital Visit Rate After Outpatient Colonoscopy and 7-Day Hospital Visit Rate After Outpatient Surgery measures.

The aforementioned tiered measures are only examples for the purposes of this request for comment to further discussion of this concept for the REHQR Program.

Such reporting could be phased-in; for example, as suggested by the commenter, all REHs could report the Tier 1 quality measures beginning at a designated time after their REH status began, and all REHs providing

[596] Centers for Medicare & Medicaid Services. Pre-Rulemaking MUC Lists and MAP Reports. The Measures Management System. Available at: https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.

[597] Healthcare Access in Rural Communities. Rural Health Information Hub. Available at: *https://www.ruralhealthinfo.org/topics/healthcare-access. Last accessed March 13, 2023.*

[598] Ibid.

[599] Section 1861(kkk)(2)(C) of the Act.

[600] Rural Telehealth and Healthcare System Readiness Measurement Framework Final Report (2021). Accessed March 28, 2023. Available at: *https://www.qualityforum.org/Publications/2021/11/Rural_Telehealth_and_Healthcare_System_Readiness_Measurement_Framework__Final_Report.aspx.*

[601] Ibid.

[602] Federal Office of Rural Health Policy (FORHP). MBQIP Measures (January 2023)—Current Medicare Beneficiary Quality Improvement Project (MBQIP) Measures. Available at: *https://www.ruralcenter.org/sites/default/files/2023-02/MBQIP-Measures.pdf.*

[603] See section 1861(kkk)(1) of the Act.

additional services would begin to submit Tier 2 data at a designated time after such services begin under the new REH status.

We invite public comment on the implementation of a tiered quality measure approach in the REHQR Program, considerations in designing the structure of a tiered framework, the number of measures in each tier, and considerations for designating measures for tiers of such a framework.

8. Proposal To Display Quality Measure Data Publicly

a. Public Reporting of Quality Data Generally

Pursuant to the CAA, the Secretary shall establish procedures to make quality measure data submitted by REHs available to the public on a CMS website.[604] Such procedures shall ensure that the REH has the opportunity to review, and submit corrections for, the data that is to be made public with respect to the REH prior to such data being made public.[605] In this proposed rule, we propose to align our approach to the public display of measures with that of the Hospital OQR and ASCQR Programs. For detail on the public display of measures in the Hospital OQR and ASCQR Programs, we refer readers OPPS/ASC final rules of CY 2009 (73 FR 68777 through 67779), CY 2014 (78 FR 75092), and CY 2017 (81 FR 79791). We propose to make publicly reported data under the REHQR Program available to the public both on our Care Compare website and in downloadable data files located in the Provider Data Catalog (PDC), found at *http://data.cms.gov.* We intend to display these data publicly for any consumer or other member of the public beginning with measure data submitted relevant to services provided in CY 2024. To the extent possible, in order to publicly display these data, we will use the same information systems, business processes, and other infrastructure that we use to display data for the Hospital OQR and Hospital Inpatient Quality Reporting (IQR) Programs. This alignment of processes and policies will enhance alignment with other quality reporting programs and ease of understanding for REHs.

We also propose that participating REHs would be granted the opportunity to review their data before the information is published during a 30-day review and corrections period (the preview process). Similarly, to the Hospital OQR and Hospital IQR Programs, we would announce the timeframes for the preview period starting with the measure data submitted relevant to services provided in CY 2024 on a CMS website, such as QualityNet, or on applicable listservs. We generally strive to display hospital quality measures data on the designated website as soon as possible after measure data have been submitted to CMS. However, if there are unresolved display issues or pending design considerations, we may make the data available on other, non-interactive, CMS websites. This preview process aligns with that of the Hospital OQR Program (81 FR 79791).

We propose to codify this policy at § 419.95 by adding paragraph (f) ''Public Reporting of Data Under the REHQR Program.'' In proposed paragraph (f), we propose that data that an REH submits for the REHQR Program would be made publicly available by a CMS Certification Number (CCN) on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public.

We invite public comment on this proposal.

b. Public Reporting of Proposed REHQR Program Claims-Based Measures

We propose to make measure scores for claims-based measures proposed for the REHQR Program measure set publicly available beginning with measure data submitted relevant to services provided in CY 2024. As discussed above in section XVI.B.5 of this proposed rule, we propose to adopt the following three claims-based measures into the REHQR Program measure set: (1) Abdomen CT measure, (2) 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, and (3) 7-Day Hospital Visit Rate After Outpatient Surgery measure.

Public reporting measure data for a claims-based measure would not begin until completion of a data collection period specific to that claims-based measure, provided sufficient case volumes are achieved.[606] [607] For example, for the 7-Day Hospital Visit Rate After Outpatient Colonoscopy measure, the data collection period is three years; public reporting would begin after completion of an initial three-year data collection period, or CY 2027, provided the hospital had sufficient case volumes. We plan to provide additional detail on the timeline of publicly reporting this data in future rulemaking.

The display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs. The data would be available to the public both on our Care Compare website and in downloadable data files located in the Provider Data Catalog (PDC), found at *http://data.cms.gov*. Data associated with these three claims-based measures would be updated annually.

We invite public comment on this proposal.

c. Public Reporting of the Proposed Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure

In the Hospital OQR Program, only data for two out of the four strata of the Median Time for Discharged ED Patients measure are reported publicly. Measure data for the Median Time for Discharged ED Patients—Reported Rate is currently publicly displayed on the Care Compare site and in the downloadable data files located in the PDC, found at *https://data.cms.gov*, for the Hospital OQR Program. Additionally, measure data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients is publicly displayed in downloadable data files located in the PDC, in order to address a behavioral health gap in the publicly reported Hospital OQR Program measure set.[608]

While data for the Median Time for Discharged ED Patients—Transfer Patients measure stratification is not currently reported publicly for hospitals participating in the Hospital OQR Program, we believe publicly reporting measure data for this stratum for REHs is imperative to allow for the identification of REH ED throughput performance gaps for patients requiring higher levels of specialized care above what an REH is able to provide. Likewise, data for the Median Time for Discharged Patients—Overall Rate measure stratification are not currently reported publicly for hospitals participating in the Hospital OQR

[604] CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

[605] CAA, 2021, at section 125(a)(1)(B) of Division CC, adding section 1861(kkk)(7)(D) of the Act.

[606] CMS does not report measures publicly unless measures are the result of an analysis of more than 10 cases.

[607] CMS Policy for Privacy Act Implementation & Breach Notification, July 23, 2007, Document Number: CMS–CIO–POL–PRIV01–01, p 4. Statistical, aggregate or summarized information created as a result of analysis conducted using identifiable CMS data obtained under CMS-approved projects/studies may only be disclosed if the data are not individual-specific and the data are aggregated to a level where no data cells contain 10 or fewer individuals.

[608] CMS adopted a policy to publicly report measure data for the Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients in the CY 2018 OPPS/ASC final rule (82 FR 59437).

Program. However, we believe publicly reporting measure data for this stratum for REHs participating in the REHQR Program is important to provide an account of all patients seen in the REH's ED, beyond identifying specific performance in certain patient populations as reflected by the other strata calculated for this measure. We note that the Median Time for Discharged ED Patients measure is of particular importance for the REHQR Program because care provided in EDs will likely be a focus of REH services; as such, we seek to provide transparency in publicly reporting of all the strata calculated for this measure. For a more detailed discussion of our proposal to adopt the Median Time for Discharged ED Patients measure in the REHQR Program, please refer to section XVI.B.5.b of this proposed rule.

We propose to make publicly available data received from REHs to calculate the following measure strata for the Median Time for Discharged ED Patients measure: (1) Median Time for Discharged ED Patients—Overall Rate; (2) Median Time for Discharged ED Patients—Reported Measure; (3) Median Time for Discharged ED Patients—Psychiatric/Mental Health Patients; and (4) Median Time for Discharged ED Patients—Transfer Patients. We intend to display these data publicly beginning with the first quarter of measure data submitted relevant to services provided in CY 2024 in which case thresholds are met. We plan to provide additional detail on the timeline of publicly reporting this data in future rulemaking. As discussed above, display of these data would rely on the same business processes and resources that are currently in use for the Hospital OQR and Hospital IQR Programs.

We invite public comment on these proposals.

C. Administrative Requirements

1. Proposal To Codify Administrative Requirements

Section 1861(kkk)(7)(B)(i) of the Act provides that, with respect to each year beginning with 2023, or each year beginning on or after the date that is one year after one or more measures are first specified under section 1861(kkk)(7)(C) of the Act, an REH shall submit data to the Secretary in accordance with section 1861(kkk)(7)(B)(ii). Clause (ii) states that, with respect to each such year, an REH shall submit to the Secretary data on quality measures in a form and manner, and at a time, specified by the Secretary for purposes of section 1861(kkk)(7)(B) of the Act.

We finalized foundational administrative requirements for REHs participating in the REHQR Program in the CY 2023 OPPS/ASC final rule (87 FR 71752, and 72149 through 72150). In that rule, we require REHs must (1) register on a CMS website before beginning to report data; and (2) identify and register a security official as part of that registration process. We also require REHs to submit data on all quality measures to CMS. We propose to codify the participation requirements in the REHQR Program at § 419.95(b) ''Participation in the REHQR Program.''

We note that we intend to propose additional administrative requirements as appropriate for the REHQR Program in subsequent rulemaking.

We invite public comment on these proposals.

D. Form, Manner, and Timing of Data Submitted for the REHQR Program

1. Proposal To Align and Codify Submission of REHQR Program Data

We refer readers to the CYs 2014, 2016, and 2018 OPPS/ASC final rules (78 FR 75110 through 75111; 80 FR 70519 through 70520; and 82 FR 59439, respectively) where we finalized our policies for clinical data submission for the Hospital OQR Program. We codified these submission requirements at § 419.46(d). We propose to align the policies regarding submission of program data for the REHQR Program with those from the Hospital OQR Program.

We also propose to codify this policy at § 419.95 by adding paragraph (c) ''Submission of REHQR Program Data.'' In proposed paragraph (c)(1), we would require that REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner, and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes. In proposed paragraph (c)(2), we propose that submission deadlines by measure and by data type be posted on a CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or executive order would be extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a nonwork day for Federal employees by statute or executive order.

We invite public comments on these proposals.

2. Proposed Requirements for Chart-Abstracted Measures Where Patient-Level Data Are Submitted Directly to CMS Beginning With the CY 2024 Reporting Period

We propose to adopt one initial chart-abstracted measure for the CY 2024 reporting period and for subsequent years: Median Time for Discharged ED Patients. Measure data for this measure would be submitted via the HQR System (formerly referred to as the QualityNet Secure Portal). In developing this proposal, we also considered proposing that REHs submit data for this measure on an annual rather than quarterly basis to help reduce burden for REHs participating in the REHQR Program. However, we note that REHs would have been reporting this measure on a quarterly basis under the Hospital OQR Program and would thus be acclimated to this reporting frequency. Therefore, to enhance alignment with this program, we propose a similar data submission frequency on a quarterly basis. We refer readers to the CY 2015 OPPS/ASC and CY 2023 OPPS/ASC final rules for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964; 87 FR 72110 to 72112).

Beginning with the CY 2024 reporting period, the applicable patient encounter quarters for chart-abstracted data and their corresponding data submission deadlines are as follows in Table 83.

TABLE 83: CY 2024 Reporting Period and Subsequent Years*

Patient Encounter Quarter	Clinical Data Submission Deadline
Q1 2024 (January 1 – March 31)	08/01/2024
Q2 2024 (April 1 – June 30)	11/01/2024
Q3 2024 (July 1 – September 30)	02/01/2025
Q4 2024 (October 1 – December 31)	05/01/2025

*All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a nonwork day for Federal employees by statute or executive order would be extended to the first day thereafter.

We propose to adopt these dates as deadlines for submitting chart-abstracted measure data for the REHQR Program.

We invite public comment on this proposal.

3. Proposed Claims-Based Measure Data Requirements Beginning With the CY 2024 Reporting Period

We propose to adopt three initial claims-based measures for the CY 2024 reporting period and for subsequent years: Abdomen CT; 7-Day Hospital Visit Rate After Outpatient Colonoscopy (CBE #2539); and 7-Day Hospital Visit Rate After Outpatient Surgery (CBE #2687). In calculating these and future claims-based measures, we propose to use Medicare claims data for services with encounter dates on or after January 1, 2024.

We invite public comment on this proposal.

4. Proposal To Adopt and Codify a Review and Corrections Period for Measure Data Submitted to the REHQR Program

In the event that an REH submits data for a measure, such as the chart-abstracted Median Time for Discharged ED Patients measure proposed for adoption in section XVI.B.5.b of this proposed rule, and later discovers or suspects the data provided were not accurate, it may need to submit corrected data. To address this need, we propose to adopt the same policies currently in place for the Hospital OQR Program. Under the Hospital OQR Program, hospitals submit chart-abstracted data to CMS on a quarterly basis. These data are typically due approximately four months after the quarter has ended. We refer readers to the CY 2015 OPPS/ASC final rule for a discussion of our previously finalized policies regarding submissions deadlines for chart-abstracted measures for the Hospital OQR Program (79 FR 66964).

Hospitals are encouraged to submit data early in the submission schedule so that they can identify errors and resubmit data before submission deadlines. Hospitals can continue to review, correct, and change these data up until the close of each submission deadline. For example, under the Hospital OQR Program, we finalized a 4-month period as the review and corrections period for chart-abstracted data (79 FR 66964). During this review and corrections period, hospitals can enter, review, and correct data submitted directly to CMS. However, after the submission deadline, hospitals would not be allowed to change these data. Under the Hospital OQR Program, we generally provide rates to hospitals for the measures that have been submitted for chart-abstracted, patient-level data 24 to 48 hours following submission deadline.

We propose to adopt this same policy under which an REH may review and submit corrections to measure data, and that for chart-abstracted measure data, an REH may review and submit corrections to measure data submitted for a period of four months after the reporting quarter has ended. We also propose to codify this policy at § 419.95 by adding paragraph (c)(3) ''Review and Corrections Period.'' In proposed paragraph (c)(3), we propose that REHs would have a review and corrections period for all quality data submitted, which runs concurrently with the data submission period, when they would be able to enter, review, and correct data submitted prior to the submission deadline. In addition, we propose that after the submission deadline, these data cannot be changed.

We invite public comment on this proposal.

5. Extraordinary Circumstances Exceptions (ECE) Process

a. Proposal To Adopt an ECE Process for the REHQR Program

In our experience, there have been times when facilities have been unable to submit information to meet program requirements due to extraordinary circumstances that are not within their control. It is our goal not to penalize such entities for such circumstances and we do not want to unduly increase their burden during these times. We propose an Extraordinary Circumstances Exceptions (ECE) process for REHs to request and for CMS to grant extensions or waivers with respect to the reporting of required quality data when there are extraordinary circumstances beyond the control of the REH. Under this proposed process, CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. Because we do not anticipate that such systemic errors will happen often, we do not anticipate granting exceptions on this basis frequently.

We propose that CMS may grant an exception to one or more data submission deadlines and requirements upon request by an REH, pursuant to specific requirements for submission of such a request described below. In addition, we propose that CMS may grant exceptions at its own discretion, without an accompanying request from an affected REH, when CMS determines that an extraordinary circumstance has occurred.

For an REH to request consideration of an exception to the requirement to submit quality data or medical record documentation for one or more quarters, the REH would follow specific requirements for submission of an ECE request form available on a CMS website. We note that the following information must appear on the request form: the REH's CCN; the REH's name; the REH's CEO or other REH-designated personnel contact information, including name, email address, telephone number, and mailing address (must include a physical address, a post office box address is not acceptable); REH's reason for requesting an exception; evidence of the impact of the extraordinary circumstances, including

but not limited to photographs, newspaper and other media articles; and a date when the REH believes it would again be able to submit REHQR Program data and/or medical record documentation, and a justification for the proposed date.

The request form must be signed by the REH's designated contact, whether or not that individual is the CEO. A request form is required to be submitted within 90 days of the date that the extraordinary circumstance occurred. Following receipt of such a request, CMS would provide an email acknowledgement using the contact information provided in the request notifying the designated contact that the REH's request has been received and following CMS' decision, CMS would notify the REH using the same contact information. In the case where CMS grants exceptions to REHs that have not requested them because we determine that an extraordinary circumstance has occurred in a region or locale, we would communicate this decision to REHs and vendors through routine communication channels, including but not limited to emails and notices on a CMS website.

We also propose to codify these policies at § 419.95 by adding paragraph (g), ''Exception.'' In proposed paragraphs (g)(1) and (g)(2), we propose that we may grant, upon the request of the REH or at our discretion, an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the REH.

We invite public comment on this proposal.

XVII. Changes to Community Mental Health Center (CMHC) Conditions of Participation (CoPs)

A. Background and Statutory Authority

The Consolidated Appropriations Act (CAA) of 2023 (Pub. L. 117–328) was signed into law on December 29, 2022. Section 4124 of division FF of this legislation established coverage of intensive outpatient services (IOP) in community mental health centers (CMHC). Section 4124 of the CAA, 2023 extends Medicare coverage and payment of IOP services furnished by a CMHC beginning January 1, 2024, allowing coverage of both partial hospitalization services (PHP) and IOP services to be furnished by CMHCs at section 1832(a)(2)(J) of the Act. Additionally, the CAA, 2023 revised section 1861(ff) of the Act to define IOP services while also amending the definition of PHP services. The statutory definitions provide distinctions between the two programs for Medicare purposes.

Section 1861 (ff)(3)(B)(iv) of the Act authorizes the Secretary to establish the requirements that a CMHC must meet to participate in the Medicare Program, and these CoPs are set forth in regulations at 42 CFR part 485, subpart J (42 CFR 485.900). On October 29, 2013, we published a final rule in the **Federal Register** titled ''Medicare Program: Conditions of Participation (CoP) for Community Mental Health Centers'' (78 FR 64604), hereinafter referred to as ''2013 CoP CMHC final rule'', which established CoPs for CMHCs.

In order to implement division FF, section 4124 of the CAA, 2023, we propose to modify the requirements for the CMHC to include IOP services throughout the CoPs.

Under section 1861(ff)(3)(B)(iii) of the Act, a CMHC must provide at least 40 percent of its services to individuals who are not eligible for Medicare Part B. This requirement is reflected in the CoPs at § 485.918(b)(1)(v).[609] Under this requirement, CMHCs must submit a self-attestation certification statement upon initial application to enroll in Medicare, and as a part of revalidation, including any off-cycle revalidation. Medicare enrollment will be denied or revoked in instances where the CMHC fails to provide the certification statement as required. In addition, Medicare enrollment will also be denied or revoked if the 40 percent requirement, as specified in section 1861(ff)(3)(B)(iii) of the Act and § 485.918(b)(1)(v), is not met. We solicit public comment on how the provision of IOP services may impact the populations CMHCs serve as well as the potential impact on meeting the 40 percent requirement.

We also propose to revise the personnel qualifications of Mental Health Counselors (MHCs) and add personnel qualifications of Marriage and Family Therapists (MFTs) to the CMHC CoPs. Division FF, section 4121 of the CAA, 2023, establishes a new Medicare benefit category for MHC services and MFT services furnished by and directly billed by MHCs and MFTs, respectively. At the time of publication of the 2013 CoP CMHC final rule (78 FR 64604), there were no specific personnel requirements (for purposes of the Medicare program) for Mental Health Counselors (MHCs). We believe it was necessary to recognize and outline specific personnel requirements for MHCs due to their integral role in providing mental health services to CMHC clients. We believe that MFTs are also essential mental health professionals who may furnish services in a CMHC, and propose adding MFTs to § 485.904 Condition of participation: Personnel qualifications. According to the American Association for Marriage and Family Therapy, a professional association for the MFT field, one of the settings an MFT may practice is in a CMHC.[610] The CAA 2023 does not require CMHCs to employ MFTs or MHCs; however, we believe the services provided by both MHCs and MFTs are integral to ensuring the health and safety of CMHC clients. We seek comment on the revised personnel qualifications for MHCs.

B. Provisions of the Proposed Rule

Section 4124 of the CAA, 2023 provides intensive outpatient services to be included as services provided by CMHCs under the Medicare Program. We propose the following revisions to the CMHC CoPs.

1. § 485.900 Basis and Scope

Currently, a CMHC may receive Medicare payment for partial hospitalization services if it meets the CMHC CoPs. Our regulations are intended to protect the health and safety of CMHC clients and support quality care. We propose to update the CoPs for CMHCs to reflect the statutory addition of IOP services provided by CMHCs to protect the health and safety of clients. Both PHP and IOP services are outpatient mental health services for adults and children who have an acute mental illness, including, but not limited to, conditions such as depression, schizophrenia, and substance use disorders. The Medicare Statute authorizes the PHP program for clients that need a higher level and intensity of care, a minimum of 20 hours per week (section 1861(ff)(1) of the Act). A Medicare beneficiary qualifies if they otherwise require inpatient psychiatric care in the absence of such services (section 1835(a)(2)(F) of the Act). The PHP program may assist in transitioning from these institutional settings to community-based services. PHP and the addition of IOP services are important components in the continuum of mental health care and services. Both PHP and IOP are more intensive than office-based counseling but less intense than inpatient psychiatric care. Both PHP and IOP programs can serve beneficiaries as a step-up in care if additional support is

[609] *https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#.*

[610] *https://www.aamft.org/Consumer_Updates/MFT.aspx.*

needed or a step down in managing symptoms. The addition of IOP services in a CMHC would assist in ensuring the continuum of coverage of outpatient mental health services under the Medicare program. Medicare coverage of IOP services may help address barriers to access to mental health care, which may also address inequities in mental health care and services. In order to implement division FF, section 4124 of the CAA, 2023, we propose to modify the CMHC CoP at § 485.900(a)(1) through (a)(3). These modifications would allow CMHCs to receive payments for IOP services under Medicare Part B, establish requirements for the provision of IOP services in CMHCs, provide IOP services to clients, and include IOP services in the Medicare provider agreement.

2. § 485.904 Personnel Qualifications

Section § 485.904 of the CMHC CoP establishes staff qualifications, and paragraph (a) requires all professionals who furnish services directly, under an individual contract, or under arrangements with a CMHC to be legally authorized (licensed, certified, or registered) in accordance with applicable Federal, State and local laws, and be required to act only within the scope of their State licenses, certifications, or registrations. The staff qualifications set out at § 485.904(b), *Standard: Personnel qualifications for certain disciplines,* are consistent with, or similar to, those set forth in CoPs for other provider types in the Medicare regulations. As part of the 2013 CMHC CoP final rule, we established personnel qualifications for MHCs at § 485.904(b)(5). Division FF, section 4124 of the CAA, 2023, established a new Medicare benefit category for MFTs and MHC services in section 1861(lll) of the Act, including a definition for MFTs in section 1861(lll)(2) of the Act and MHCs in section 1861(lll)(4) of the Act. Section 1861(lll)(4) of the CAA 2023 defines the term 'mental health counselor' to mean an individual who: (1) possesses a master's or doctor's degree which qualifies for licensure or certification as a mental health counselor, clinical professional counselor, or professional counselor under the State law of the State in which such individual furnishes the services described in paragraph (3); (2) is licensed or certified as a mental health counselor, clinical professional counselor, or professional counselor by the State in which the services are furnished; (3) after obtaining such a degree has performed at least 2 years of clinical supervised experience in mental health counseling; and (4) meets such other requirements as specified by the Secretary. Section 1861(lll)(2) of the Act defines the term 'marriage and family therapist' to mean (1) possesses a master's or doctor's degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law of the State in which such individual furnishes the services described in paragraph (1); (2) is licensed or certified as a marriage and family therapist by the State in which such individual furnishes such services; (3) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and (4) meets such other requirements as specified by the Secretary.

To support the health and safety of CMHC clients and to promote consistency and clarity of CMHC personnel qualifications, we believe it is best to align the personnel qualifications for MFTs and MHCs with the requirements set out in the CAA, 2023. The statutory requirements for MHCs and MFTs are being codified in the CY 2024 Physician Fee Schedule proposed payment rule that is published elsewhere in the **Federal Register**. We propose to modify the MHC personnel requirement at § 485.904(b)(5) by cross-referencing the definition of an MHC at § 410.54 and adding a new requirement at § 485.904(b)(12), cross-referencing the definition of an MFT at § 410.53.

3. § 485.914 Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client

The requirements at § 485.914 establish requirements for admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client in accordance with sections 1835(a)(2)(F) and 1861(ff) of the Act. These CoPs identify general areas that would be included in a client assessment and the timeframes for completing the assessments to help the CMHC ensure it is identifying the needs in all areas in a timely fashion. At § 485.914(a)(1), we require that clients are assessed and admitted to receive partial hospitalization (PHP) services, and (2) the CMHC must also meet separate requirements as specified in § 485.918(f). The requirements at § 485.918(f) reference additional PHP requirements of 42 CFR part 410 (CMHC services and definition) and § 424.24(e) (the content of the certification and plan of treatment requirements). We propose to modify the current CoP at § 485.914(a)(2) to add IOP requirements and reference applicable requirements the CMHC must meet that are specific to IOP services at proposed § 485.918(g). This proposed standard for IOP is discussed later in section XVII.A.5 of this proposed rule.

Currently, § 485.914(d) requires that the CMHC update each client's comprehensive assessment through the CMHC interdisciplinary treatment team, in consultation with the client's primary health care provider (if any), when changes in the client's status, responses to treatment, or goal achievement have occurred and in accordance with current standards of practice. Section 485.914(d)(2) requires that the assessment must be updated no less frequently than every 30 days for clients that receive PHP services. We note that this aligns with the changes made in section 4124(a) of the CAA, 2023 to the definition of ''partial hospitalization services'' in section 1861(ff)(1) of the Act, which requires that a physician determine (not less frequently than monthly) that a client has a need for such services. This update includes information on the client's progress toward desired outcomes, a reassessment of the client's response to care and therapies, and the client's goals. We believe that for some clients, more frequent reviews are necessary since clients with ongoing mental illness may be subject to frequent and/or rapid changes in status, needs, acuity, and circumstances, and the client's treatment goals may change, thereby affecting the type and frequency of services that should be furnished. The CMHC interdisciplinary treatment team uses assessment information to guide necessary reviews and/or changes to the client's active treatment plan.[611] Currently, § 485.914(d)(2) addresses how often a CMHC must update a PHP client's assessment, and we propose to add IOP requirements to this standard, using the same period (30 days).

4. § 485.916 Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services

The review and update of the CMHC client's person-centered active treatment plan plays an integral role in outlining the care and services provided by the CMHC. The current requirements at § 485.916(d) indicate that the active treatment plan be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. The active treatment plan is reviewed at specified intervals

[611] *https://www.reginfo.gov/public/do/PRAOMBHISTORY?ombControlNumber=0938-1245#.*

but no less frequently than every 30 calendar days. Under this current requirement, the revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. In addition, the CMHC is required to meet partial hospitalization program requirements specified under § 424.24(e).

We propose to modify language at § 485.916(d) to include IOP requirements and a specific reference to the proposed requirement at § 424.24(d). As the CMHC must meet partial hospitalization program requirements specified under § 424.24(e), they must meet IOP program requirements specified under § 424.24(d) if such services are included in the active treatment plan.

5. § 485.918 Organization, Governance, Administration of Services, Partial Hospitalization Services

The CoP at § 485.918 establishes requirements for CMHC organization, governance, administration of services, and partial hospitalization services. This standard includes administrative and governance structure standards and clarifies the governing body's expectations. Other requirements under this standard are professional management responsibility, staff training, and physical environment. The overall goal of this CoP is to ensure that the management structure is organized and accountable. The requirement at § 485.918(b), Standard: Provision of services, specifies a comprehensive list of services that a CMHC is required to furnish. This list of services that CMHCs provide corresponds directly to the Act's statutory requirements in section 1861(ff)(3).

We propose to modify the section heading at § 485.918 by adding ''intensive outpatient services,'' such that the new section heading will be ''Organization, governance, administration of services, partial hospitalization services, and intensive outpatient services.''

In addition, we propose to add IOP to the requirement at § 485.918(b)(1)(iii) for the provision of services. These proposed changes would recognize IOP, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or an inpatient or residential setting or psychosocial rehabilitation services.

We propose to redesignate the current requirements at § 485.918(g) to paragraph (h) and add a new standard for IOP services at § 485.918(g). This new requirement would specify the additional requirements a CMHC providing IOP services must meet based on the proposed requirements at § 410.2, § 410.44, § 410.111, and § 424.24(d) of this chapter. See section VIII.B.2 and VIII.C.2 of this proposed rule for a discussion of these additional requirements.

We solicit public comments on each of our proposals. In addition, we request comments from CMHC stakeholders regarding the impact of the proposed IOP requirements on the requirement that CMHCs provide at least 40 percent of their items and services to individuals who are not eligible for benefits under title XVIII of the Act, as specified at § 485.918(b)(1)(v). Specifically, we seek comment on the following:

- Do you expect the total number of clients served in your CMHC to increase with the addition of IOP?
- Do you expect that your CMHC would admit new clients directly into the IOP program, and do you have a sense of their anticipated insurance status?
- Do you expect that any of your PHP clients would step down to the IOP program? If so, can you provide an estimated percentage of PHP clients who would step down to the IOP program?
- Do you expect any of your outpatient treatment clients, such as office-based therapy, to step up to the IOP program?
- Do you expect that offering IOP would impact your ability to meet the 40 percent requirement at § 485.918(b)(1)(v)? This requirement states that the CMHC provides at least 40 percent of its items and services to individuals who are not eligible for benefits under title XVIII of the Act.

XVIII. Proposed Updates to Requirements for Hospitals To Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled ''Bringing Down the Cost of Health Care Coverage,'' requires each hospital operating within the United States (U.S.) for each year to establish and update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Social Security Act (the Act). Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services (Secretary) to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

In a final rule dated November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF);[612] and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180. We also explained our belief that these two different methods of making hospital standard charges public are necessary to ensure that such data are available to consumers where and when they are needed, including through data aggregation methods (for example, via integration into price transparency tools, electronic health records (EHRs), and consumer apps), and direct availability to consumers searching for hospital-specific charge information. Additionally, we believe such data can be used specifically by employers, researchers, and policy officials, and similar members of the public to help bring more value to healthcare.

Subsequently, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941), we strengthened the hospital price transparency (HPT) enforcement scheme in order to improve compliance rates and made other updates to the requirements. Specifically, we (1) increased the penalty amount for noncompliance through the use of a scaling factor based on hospital bed count; (2) deemed state forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180, and (3) prohibited certain conduct that we concluded were barriers to accessing the standard charge information, including, specifically, prohibiting hospitals from coding their MRF in a fashion that made it inaccessible to automated searches and direct downloads.

In both of those final rules, we stated that our policies requiring public release of hospital standard charge information

[612] We have previously generally described the machine-readable file (MRF) as a single digital file that is in a machine-readable format (as defined at 45 CFR 180.20), and we propose in this proposed rule to codify that definition in our regulations.

are a necessary and important first step in ensuring transparency in healthcare prices for consumers. We also recognize that the release of hospital standard charge information is not itself sufficient to achieve our ultimate price transparency goals. The regulations are, therefore, designed to begin to address some of the barriers that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs.

2. Summary of Proposals in This Proposed Rule

We propose to amend several of our HPT requirements in order to improve our monitoring and enforcement capabilities by improving access to, and the usability of, hospital standard charge information; reducing the compliance burden on hospitals by providing CMS templates and technical guidance for display of hospital standard charge information; aligning, where feasible, certain HPT requirements and processes with requirements and processes we have implemented in the Transparency in Coverage (TIC) initiative; and making other modifications to our monitoring and enforcement capabilities that will, among other things, increase its transparency to the public. Specifically, we propose to: (1) define several terms; (2) revise the standard charge information and data elements that hospitals must include in their MRFs, as well as require hospitals to use a template developed by CMS (hereafter referred to as a 'CMS template') for purposes of complying with § 180.50 of our regulations, in order to standardize the displayed MRF data; (3) improve the accessibility of the hospital MRF by requiring hospitals to include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the MRF; and (4) improve our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

B. Proposal To Modify the Requirements for Making Public Hospital Standard Charges at 45 CFR 180.50

In the CY 2020 HPT final rule, we finalized, at 45 CFR 180.50, specific requirements with which hospitals must comply for the purpose of making public a single comprehensive list of standard charges for the items and services they provide, including requirements that govern the format, data elements, location and accessibility of the list, as well as the frequency by which they must update the list.

In this section, for the reasons discussed below, we propose to substantially modify § 180.50(a) through (d) of our regulations, which govern some of the requirements for how hospitals must make public their standard charges for all items and services they provide. Specifically, we propose to (1) define several new terms; (2) require hospitals to affirm the accuracy and completeness of the standard charges displayed in the MRF; (3) require hospitals to display additional data elements in their list of standard charges; (4) require display of standard charge information using a CMS template; and (5) adopt new requirements to improve the automated accessibility of the machine-readable file.

1. Proposed Definitions

We propose to add the following definitions to § 180.20:

- ''CMS template'' means a CSV format or JSON schema that CMS makes available for purposes of compliance with the requirements of § 180.40(a).
- ''Consumer-friendly expected allowed amount'' means the average dollar amount that the hospital estimates it will be paid by a third party payer for an item or service.
- ''Encode'' means to enter data items into the fields of the CMS template.
- ''Machine-readable file'' means a single digital file that is in a machine-readable format.

In light of these proposed definitions, we further propose several technical and conforming revisions to ensure consistency of the use of these terms across the regulation. Specifically, we propose to replace references to ''the file'' and ''the digital file'' in § 180.50(d)(4) through (5) with the proposed defined term ''machine-readable file''. Revisions to references to the ''file'' in the introductory text of § 180.50(c) and at § 180.50(e) are addressed as a part of other proposed changes within this proposed rule.

2. Proposal To Require Hospitals To Affirm the Accuracy and Completeness of Their Standard Charge Information Displayed in the MRF

Since we implemented the HPT regulations, we have received questions from the public regarding the accuracy and completeness of the standard charge information displayed by hospitals. Similar questions have also arisen in the course of our enforcement activities. Section 2718(e) of the PHS Act requires hospitals to make public each standard charge the hospital has established; however, a hospital may not have established certain types of standard charges defined by the regulation. For example, under our current regulations, a hospital that has not established any discounted cash prices for any item or service would not have any discounted cash prices to display in its MRF. Depending on the type of MRF format chosen by the hospital, the file may contain 'blanks' without explanation. Although a hospital that chooses to leave the discounted cash price field blank under this scenario would be in compliance with our regulations, a user of the MRF could be unsure as to whether the hospital has not established such charges, or, instead, has not complied with the requirement to disclose them in the MRF. Although many hospitals include explanatory information on the web page associated with the MRF or within the MRF itself (for example, in a CSV format, inserting 'N/A' in blank cells or adding an explanatory note), they currently do so on a voluntary basis.

We believe that requiring the hospital to affirm the accuracy and completeness of its MRF would mitigate the potential for public confusion as to whether the MRF is accurate and complete because it clarifies to the public that blank cells left in some formats (such as CSV which can be opened in a human-readable format) are intentional. Such an affirmation would also streamline our enforcement efforts by removing the need to initiate a compliance action asking for the hospital to verify that their file is accurate and complete. We therefore propose to require that each hospital affirm directly in its MRF (using a CMS template, which we propose in more detail at XVIII.B.2 of this proposed rule) that it has included all applicable standard charge information in its MRF as of the date in the MRF. We believe that requiring the hospital to add this affirmation directly in its MRF would make it clear to the public that the affirmation relates directly to that MRF, and would mitigate the potential for confusion if

we only required that the affirmation appear on a website that links to the hospital's MRF, especially if that website also links to other hospital MRFs.

We therefore propose to add new paragraph (a)(3) at § 180.50 to require that, in its MRF, each hospital add a statement affirming that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in its MRF, in accordance with the requirements of § 180.50, and that the information displayed is true, accurate, and complete as of the date indicated in the file.

We seek comment on this proposal.

3. Proposal To Improve the Standardization of Hospital Machine-Readable File (MRF) Formats and Data Elements

In this section, we propose to revise several requirements at § 180.50(b) and (c). We also propose to adopt technical edits to other sections of the HPT regulations that are related to the revisions for alignment, conformity, and clarity.

a. Background

In the CY 2020 HPT final rule, we expressed our concern that lack of uniformity in the way that hospitals display their standard charges leaves the public unable to meaningfully use, understand, and compare standard charge information across hospitals (84 FR 65556). We stated that we agreed with commenters that standardization in some form is important to ensure high utility for users of hospital standard charge information, and we finalized an initial set of rules for making public all standard charges in an MRF at § 180.50. Section 180.50(a)(1) of our regulations states that a hospital must establish, update, and make public a list of all standard charges for all items and services online in the form and manner specified in that section, and § 180.50(a)(2) states that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. If a hospital location operating under a single hospital license or approval shares the same set of standard charges as another hospital location operating under the same license or approval, then both hospital locations may post the same MRF. In other words, in the interest of burden reduction, hospital locations may share a file so long as the standard charges information displayed in the file are applicable to the indicated locations.

Section 180.50(b) of our regulations describes the required data elements that must be included, as applicable, in the hospital's MRF, which are the following:

- Description of each item or service provided by the hospital.
- The corresponding gross charge that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding payer-specific negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting. Each payer-specific negotiated charge must be clearly associated with the name of the third party payer and plan.
- The corresponding de-identified minimum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding de-identified maximum negotiated charge that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- The corresponding discounted cash price that applies to each item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting.
- Any code used by the hospital for purposes of accounting or billing for the item or service, including, but not limited to, the CPT code, HCPCS code, DRG, NDC, or other common payer identifier.

When we finalized this set of standardized data elements, we stated our belief that they would help ensure that the public could compare standard charges for similar or the same items and services provided by different hospitals. Commenters had provided many additional suggestions for how to standardize the standard charge information displayed by hospitals, but we declined at the time to be more prescriptive in our approach. Instead, we indicated that we might revisit the requirements in future rulemaking should we find it necessary to make improvements in the display and accessibility of hospital standard charge information.

At § 180.50(c), the regulation specifies that the required (but ''as applicable'') data elements must be published in a single digital file that is in a machine-readable format. The term ''machine-readable format'' is defined at § 180.20 to mean a digital representation of data or information in a file that can be imported or read into a computer system for further processing.

Since we first implemented the regulation in January 2021, feedback in reports developed and made public by interested parties, particularly from IT specialists, researchers, employers, and others, indicates that more standardization of the files (including a specified template and standardization of additional contextual data elements) may be necessary to improve the public's use and understanding of, and ability to make comparisons among, hospital standard charge information.[613] [614] [615] [616] [617] In particular, IT specialists have indicated that the current flexibilities and lack of encoding specifications hinder the machine-readability of the data in the files, presenting a barrier to the intended use of the data. Additionally, hospitals have asked us for more specificity on how they should publicly display their standard charge information, with an emphasis on how they should explain and display their payer-specific negotiated charges. Some hospitals have suggested that a template developed by CMS could be useful to improve hospital compliance and reduce hospital burden. Further, the flexibilities that the current regulation permit insofar as the format of hospital standard charges information, and the very limited set of data elements required to be displayed under § 180.50, have presented an enforcement challenge. For example, because hospitals are permitted to display their information using a wide variety of file formats and data encoding practices, we must manually, via time and resource-intensive processes, review the information in the files to assess whether the information is consistent with the data element requirements at § 180.50(b). Some hospitals rename data elements, include additional data elements, or exclude, without explanation, data elements that are not applicable, which can make it difficult

[613] *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/.*

[614] *https://energycommerce.house.gov/events/improving-drug-pricing-transparency-and-lowering-prices-for-american-consumers.*

[615] *https://familiesusa.org/wp-content/uploads/2023/04/Power-of-Price-Transparency-final-4.19.23.pdf.*

[616] *https://blog.turquoise.health/hospital-compliance-assessments/.*

[617] *https://static1.squarespace.com/static/60065b8fc8cd610112ab89a7/t/60de0380cc0972060d0354eb/1625162631437/PRA+OPPS+Recommendations+June+2021%5B3%5D.pdf.*

to assess whether the information contained in the file is accurate and complete. This, in turn, slows compliance reviews and often requires us to engage in one-on-one discussions with hospitals. We therefore came to believe that requiring more specificity in formatting and encoding the MRFs, as well as increasing the number of required corresponding data elements hospitals must provide, would not only create efficiencies for public users of the MRFs and our efforts to enforce the requirements, but also improve the meaningfulness of the hospital's standard charges.

As a result, in the CY 2022 OPPS/ASC proposed rule (86 FR 42321), we sought comment on improving standardization of the data disclosed by hospitals in the MRF. In response, many commenters urged CMS to create a standard template for hospitals to use for posting their MRF, noting that such standardization could ease operational burdens, improve the public's (including employers and researchers) ability to make price comparisons across hospitals, and better enable third party data aggregation services to develop user-friendly consumer tools for displaying this information. Some commenters recommended that CMS work with providers and vendors to better understand the benefits of a standard template. Some hospitals also urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents and provide additional clarification on how hospitals should indicate that they have not established all five types of standard charges for a particular listed item or service.

We requested the HHS Health Federally Funded Research and Development Center (FFRDC) [618] to more fully explore the feasibility of these commenters' recommendations, and to identify technical specifications and categories of information (referred to as ''data elements'') that we could consider proposing in future rulemaking to improve the usability and meaningfulness of the standard charges display. The Health FFRDC convened a technical expert panel (TEP) and used the TEP members' advice to make informed recommendations to CMS in the summer of 2022.[619] The TEP was comprised of both MRF developers, specifically, hospitals (representatives of large and small acute and specialty care hospitals), and primary users of MRF data, specifically, researchers and information technology innovators. The TEP members discussed the challenges and complexities of displaying, in a meaningful way, all hospital standard charges in an MRF. The TEP members noted that increasing standardization of the MRF and the required data elements may improve the public's ability to make price comparisons across hospitals. TEP members indicated their belief that public display of hospital standard charge information is an important step toward transparency in prices for hospital items and services, but cautioned that hospitals use different methods to establish standard charges for items and services, resulting in charge/item and charge/service combinations that are often unique to that hospital. Therefore, some direct comparisons of hospital standard charges may continue to be a challenge if such comparisons are made under the assumption that hospitals always use the same methods to establish their standard charges and that the same charge/item and charge/service combinations are consistent across hospitals. As such, attempting to use hospital standard charges in isolation, without additional contextual information, can result in erroneous conclusions and comparisons. The members went on to discuss the potential benefits to both hospitals and the public if CMS required hospitals to display standard charge information that better described or contextualized their standard charges, including standard charge information related to complex contracting arrangements between hospitals and third party payers. The TEP also weighed the benefits with the potential burden hospitals would incur to display those new data elements and encode data in a more specified way.

First, the TEP members discussed what general machine-readable format(s) would be best suited to display hospital standard charges. The TEP members indicated that use of non-proprietary formats would be ideal because they are widely and freely available to both the developers (the hospitals) and users (for example, IT developers and researchers) of the MRFs. The TEP members then considered different types of non-proprietary formats. They first considered whether a single non-proprietary format, such as JSON, should be recommended because of its ability to represent hierarchical relationships better than tabular non-proprietary formats, such as CSV. Whereas JSON's use of a hierarchical format could be beneficial because it would eliminate the need to leave data fields, sometimes numerous, blank if the hospital has no applicable corresponding information. However, TEP members noted that existing hospital systems often produce files in CSV, and that smaller, less-resourced, hospitals often lack the in-house capacity to develop and manage a JSON file. The TEP members therefore suggested that hospitals have a choice of JSON and CSV formats. The TEP members also discussed the specific technical layout of a CSV file, including a:

- ''tall'' format, with separate payer and plan data elements that provide the benefit of static header naming with less opportunity for standardization error and that is similar to existing output files that many hospitals are using to build their MRFs; and
- ''wide'' format, with variable payer-specific negotiated charge data elements that incorporate the payer and plan name into a single column header; this may reduce the file size because many data elements would not need to be repeated as frequently.

Ultimately, MITRE, as informed by TEP members, recommended to CMS that CMS provide hospitals with an option to use one of three layouts representing two types of machine-readable formats for displaying their standard charge information in an MRFs: (1) JSON schema (plain format), (2) CSV (''tall'' format), or (3) CSV (''wide'' format). TEP members indicated that this choice would balance the need for greater standardization for automated machine use of the files, while providing a hospital some flexibility to select the least burdensome format and layout to incorporate into its current MRF development process.

The TEP also discussed the data elements, or categories of standard charge information, that they believed should be included in the MRF, with a goal of improving the public's understanding and use of hospital standard charges. These discussions focused on the challenges of displaying payer-specific negotiated charges, given the variety of ways that hospitals establish this type of standard charge, and data elements that would be necessary to help the public understand them. TEP members discussed several types of commercial contracting methodologies commonly used by hospitals to establish their payer-specific negotiated charges, including:

[618] MITRE operates HHS' Health FFRDC, a federally funded research and development center. For more information, see: *https://www.mitre.org/our-impact/rd-centers/health-ffrdc.*

[619] MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November, 2022. *https://mitre.box.com/v/MITRE-MRF-TEP.*

fee schedule, case rate, per diem, percentage of total billed (or gross) charges, and others. Ultimately, the TEP agreed on the following data elements to improve the meaningfulness and facilitate automated aggregation of hospital standard charges: (1) general information such as file version and date of most recent update of the file; (2) hospital-specific information (such as hospital name and location, license number, financial aid policy); (3) data elements corresponding to the types of standard charges defined by the HPT regulation (that is, the gross charge, payer-specific negotiated charges by payer and plan, discounted cash price, and minimum and maximum de-identified negotiated rates) and, for payer-specific negotiated charges, the type of contracting methodology and whether the payer-specific negotiated charge established by the hospital is being expressed as a dollar amount versus an algorithm or percentage; and (4) data elements that enhance understanding of the item or service to which the standard charge applies, such as a general description of the item/service, billing class (for example, whether the standard charge is billed as a facility or professional service), the hospital setting in which the item or service is provided (for example, in the inpatient or outpatient setting), drug-specific information such as the drug unit and type of measurement (such as number of milligrams), and information related to corresponding codes (such as common billing codes, revenue center codes, modifiers). TEP participants also suggested including an open field that a hospital could use, as needed, to provide additional contextual information should it believe the template's data elements are insufficient to ensure a user's understanding of a standard charge displayed in the file.

The TEP members discussed a number of other data elements,[620] but concluded that the burden on hospitals to gather and display such information would outweigh their benefit to users, or that it would be infeasible to include such information in an MRF. As such, MITRE did not recommend that CMS adopt them.

MITRE presented its findings and recommendations to CMS in the fall of 2022. After considering them, we announced in November of 2022 the availability of several 'sample formats,' that may be found on the HPT website,[621] that hospitals could voluntarily use to make public their standard charge information in an MRF. At the same time, we developed and made available a supplemental data dictionary that provides technical instructions to hospitals on how to conform to the sample formats and encode standard charge information. The sample formats and data dictionary can be found on the HPT website: *https://www.cms.gov/hospital-price-transparency/resources.* We encourage commenters to review the sample templates and data dictionary to inform their comments on these proposals.

b. Proposals To Require Hospitals To Encode All Data Items for Additional Data Elements in Their MRF

(1) Proposal To Encode, as Applicable, All Data Items in the MRF

Currently, the introductory text at § 180.50(b) states that a hospital must include all of the data elements (as specified in the paragraph) in its list of standard charges, ''as applicable''. We propose to revise the introductory text for clarity to indicate that each hospital must encode, as applicable, all standard charge information corresponding to each required data element in its MRF.

This proposed revision would differentiate the standard charge information, or data values, that must be encoded in the MRF from the ''data elements,'' or categories of data as the basis for the CMS template. The term ''data element'' is currently used at § 180.50(b) in both ways, which, at the time we implemented the regulations, seemed appropriate because of the wide latitude of flexibility we were giving hospitals to display their standard charges. However, now that we propose to require hospitals to display complete standard charge information for an expanded set of data elements and to be much more prescriptive in how such data is encoded, we believe that adopting more precise terminology will make the display requirements easier to understand.

We believe that this proposed revision is necessary in light of our other proposals to be more prescriptive in the form and manner in which hospitals display their standard charge information, and would clarify that the term ''data element'' refers to a required category of data items encoded in the MRF, and not the standard charge information itself.

Under our proposal, the term ''as applicable'' would no longer refer to data elements (which, if finalized as proposed, would all be required) and instead would qualify the standard charge information that the hospital encodes in the MRF. Hospitals would thus be required to encode its MRF with all applicable standard charge information that corresponds to each of the required data elements. We note that the phrase ''as applicable'' does not mean that encoding standard charge information that corresponds to a required data element is ''optional.'' Rather, if a hospital has established standard charge information for a required data element at proposed new § 180.50(b)(1) through (4), the hospital would be required to display that information accurately and completely, in its MRF.

(2) Proposal To Revise and Expand the Required Data Elements

At new § 180.50(b)(1) through (4), we propose to revise and expand the required data elements which describe the categories of information the hospital must encode in its MRF. We propose to include most of the data elements suggested by the TEP and recommended by MITRE in its report to CMS[622] and note that many of the proposed data elements are incorporated in the CMS 'sample formats' currently available for voluntary use by hospitals on CMS's HPT website.[623]

We propose to require hospitals to encode all applicable standard charge information for an expanded set of data elements in its MRF, which we believe would improve the public's ability to better understand and therefore more meaningfully use hospital standard charges. We believe that this expanded set of data elements will make hospital standard charges more understandable and comparable across hospitals. We

[620] Those data elements included: 'Billing Code Version' which would be the version of a code set used by providers and payers; 'Unit of Measurement' which would be used for items and services other than drugs; 'Place of Service Code' used by Medicare to indicate where in a hospital a service would be provided; 'Insurance Plan ID' such as a Health Insurance Oversight System (HIOS) identifier[620] or employer identification number (EIN) of the payer; 'Contract Expiration Date' to indicate how long a contract would be in place; 'Bundled Codes' which would indicate all individualized items and services that comprised a payer-specific negotiated rate or discounted cash price; 'Covered Services' which would indicate all the codes for services covered under a capitation arrangement; and a 'Payment Learning & Action Network' field which would indicate whether the hospital's commercial contract met criteria for different types of value-based arrangements as defined by the Learning & Action Network's Alternative Payment Model Framework (*https://innovation.cms.gov/innovation-models/health-care-payment-learning-and-action-network*).

[621] *https://www.cms.gov/hospital-price-transparency/resources.*

[622] MITRE, Hospital Price Transparency Machine-Readable File Technical Expert Panel Report and MITRE Recommendations to the Centers for Medicare & Medicaid Services, November, 2022. *https://mitre.box.com/v/MITRE-MRF-TEP.*

[623] *https://www.cms.gov/hospital-price-transparency/resources.*

decided to make these proposals after considering: the feedback discussed above; our experience with enforcing the current HPT requirements; the FFRDC recommendations as informed by their TEP; and our evolving understanding of how hospitals establish payer-specific negotiated charges with third party payers.

We agree with the feedback we have received from various interested parties, the recommendations of the FFRDC, and publicly available reports that the machine-readable data needs to be contextualized and more precisely encoded to improve the public's ability to understand and use hospital standard charges. We believe that this could largely be accomplished by requiring hospitals to conform to a CMS template layout and encode all applicable standard charge information in a consistent form and manner specified by CMS.

(a) Proposed General Data Elements

Proposed new § 180.50(b)(1) would require a hospital to encode standard charge information for each of the following ''general'' data elements:

- Hospital name(s), license number, and location name(s) and address(es) under the single hospital license to which the list of standard charges apply.

Under this proposal, a hospital would be required to include the location to which its list of standard charges applies within the MRF itself, instead of simply on its website, as is currently required at 45 CFR 180.50(d). We believe this change is necessary because we have found that a single public website may host the files of several hospitals and identify each hospital location in text on the web page. Because the hospital location is currently not listed on the file itself, the hospital information sometimes becomes disassociated from the file as it is further processed, making it difficult for end users of the data to connect standard charge information to a particular hospital, hospital location, or address. This is a result we did not intend when we finalized the initial display requirements. We believe that requiring hospitals to encode standard charge information for these data elements directly in the MRF will permit the public, including end users creating various aggregation tools, to connect the standard charge information in the file to a particular hospital's site of care as they seek to make the information more actionable. Additionally, the current requirement at § 180.50(a)(2) indicates that each hospital location operating under a single hospital license (or approval) that has a different set of standard charges than the other location(s) operating under the same hospital license (or approval) must separately make public the standard charges applicable to that location. However, there is no current requirement for a hospital to indicate under what license the hospital is operating, making enforcement of this requirement challenging. By including the license number of the hospital in the file, CMS would better be able to validate and ensure that hospitals are complying with the requirements because CMS would be able to directly connect the hospital name, license and MRF.

- The file version and date of the most recent update to the standard charge information in the MRF. First, we propose that hospitals indicate in their MRF the file version that corresponds to the CMS template that the hospital is using to display the standard charge information. File version information is necessary to provide certainty to users of the file (including CMS for purposes of automating review of MRFs) that they have coded to the correct format for processing the data. Second, we note that hospitals are currently required at § 180.50(e) to update, at least once annually, the standard charge information in the MRF and to clearly indicate the date that the standard charge information was most recently updated. Hospitals also currently have the flexibility to indicate the updated date in the file itself or otherwise in a manner that is clearly associated with the file. That flexibility would be eliminated with this proposal because we would require the date of last update to be indicated in the file itself. We therefore propose to make a necessary corresponding revision to § 180.50(e) to remove the sentence 'The hospital must clearly indicate the date that the standard charge data was most recently updated, either within the file itself or otherwise clearly associated with the file.' Requiring a hospital to include the date of the last update in the file itself is necessary for a machine to be able to automatically validate that the standard charge information in the file has been updated by the hospital at least once annually, as is required under section 2718(e) of the PHS Act and 45 CFR 180.50(e). Moreover, by placing the date of most recent update within the MRF, file users would be assured that the file they are using is the most recently available. Nothing in this proposal would prohibit a hospital from continuing to also indicate the date of the last update on its website in addition to indicating the date of the last update within its MRF.

(b) Proposals for Data Elements Related to Types of Standard Charges

First, at proposed new § 180.50(b)(2), we would consolidate into a single data element the standard charges (that is, the gross charge, payer-specific negotiated charge, de-identified minimum and maximum negotiated charge, and discounted cash price) that are currently listed as required data elements at § 180.50(b)(2) through (6). We note that this revision would remove the phrase ''that applies to each individual item or service when provided in, as applicable, the hospital inpatient setting and outpatient department setting'' from each of the individually referenced type of standard charge at § 180.50(b)(2) through (6). This concept, however, would be retained and incorporated (as addressed in more detail below) as a separate data element (''setting'') and used to contextualize hospital items and services at new § 180.50(b)(3).

Second, we would continue to require that the payer-specific negotiated charges be displayed by name of the third party payer and plan(s), each indicated as a separate data element (for example, ''payer name'' and ''plan name''). However—and as a result of our acquiring a better understanding of hospital and commercial payer contracting, we propose that hospitals may indicate plan(s) as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category. We believe this modification is necessary because we have learned that many hospital contracts are designed to negotiate the same rates across a grouping of payer plans, and not always on a plan-by-plan basis. For example, some hospitals have contracts stipulating that the payer-specific negotiated charges they establish with third party payers are for ''all plans'' offered by the third party payer, without specifying plan names. Similarly, a hospital's contract with a payer may set forth the payer-specific negotiated charges for ''all PPO plans'' or ''all managed care plans'' without listing specific plan names. As a result, hospitals would be required to indicate payer-specific negotiated charges that apply to ''Payer A'' for ''all PPO plans'', for example, rather than having to research and insert repetitious standard charge information for each named PPO plan offered by Payer A. We believe this modification is necessary to ensure hospitals are not penalized for displaying information that is consistent

with their contracting practices. Moreover, this practice could improve accessibility of the MRF by avoiding repetition of standard charge information that would unnecessarily increase file size. Additionally, because we propose to require hospitals to encode standard charge information in an MRF that conforms to a CMS template layout, the use of such template would ensure that the payer-specific negotiated charges remain 'clearly associated' with the name of each payer and plan. Accordingly, we propose to remove the phrase ''clearly associated'' from the regulatory text as a separate and distinct requirement in relationship to the data elements. Finally, we are aware of interested parties' recommendations that the payer and plan be indicated in the MRF using some uniform, nationally applicable set of abbreviations. To the extent that a uniform nationally applicable set of abbreviations is available, we seek comment on a publicly available data source(s) that we may consider as we develop the technical instructions.

Third, we propose to require that hospitals indicate the contracting method they used to establish the payer-specific negotiated charge. TEP members indicated that including the contracting method within the MRF would bring necessary context to the payer-specific negotiated charges established by the hospital. For example, a hospital may have established a payer-specific negotiated charge as a 'base rate' for a service package.[624] Without knowing that, a file user might assume that the listed payer-specific negotiated charge included every charge applicable to the provision of the item or service when, in fact, a 'base rate' charge likely would include non-standard adjustments and other added charges. Additionally, including this data element would align with the data element in the TIC template. We seek comment on contracting types that we should consider as allowed values in the CMS template, should this data element be finalized.

Fourth, we propose to require that hospitals indicate whether the payer-specific standard charge listed should be interpreted by the user as a dollar amount, percentage, or, if the standard charge is based on an algorithm, the algorithm that determines the dollar amount for the item or service. Specifying whether the number indicated as the standard charge should be interpreted as a dollar figure or percentage would ensure that the data is machine-readable and would minimize confusion about the value inserted into a particular standard charge column. Knowledge of the algorithm for a standard charge that can only be expressed as an algorithm is necessary for consumer-friendly tools to estimate in dollars an individual's payer-specific negotiated charge. Similar to the existing technical instructions for the sample templates, CMS will provide technical instructions for hospitals to display standard charges expressed in dollars, percentages, and algorithms in order to ensure consistency and machine-readability.

Fifth, we propose a consumer-friendly data element called the 'expected allowed amount' that we would require a hospital to display in situations where the payer-specific negotiated charge cannot be expressed as a dollar figure. As finalized in the CY 2020 HPT final rule, the definition of a standard charge is the 'regular rate' established by the hospital for items and services provided to a 'specific group of paying patients.' In other words, the standard charge displayed in the MRF represents the exact rate that applies to all individuals in the group, for example, all individuals covered by a particular payer and plan. This amount is generally considered to be analogous to the 'allowed amount' that is established in the contract the hospital has with the third party payer, and that appears on a patient's explanation of benefits. This is the maximum payment the plan will pay for a covered health care service, and may also be called ''eligible expense,'' ''payment allowance,'' or ''negotiated rate.''[625] A portion of this allowed amount is reimbursed to the hospital by the third party payer while the hospital bills the consumer for the remainder which is described as the 'out-of-pocket' amount. As we explained in the CY 2020 HPT final rule, knowledge of the rate the insurer has negotiated with the hospital on the consumer's behalf is essential for helping consumers determine their out-of-pocket cost estimates in advance. However, while essential, the standard charge information is not sufficient because the individual must obtain additional information from his or her third party payer related to the circumstances of their particular insurance plan (for example, what portion of the payer-specific negotiated charges would be paid by the plan and other plan dependencies such as the patient's co-insurance obligations or where the patient has not satisfied their deductible for the year).

Since implementation of the HPT regulation, hospitals have become more transparent about how they establish their payer-specific negotiated charges. Based on our experience in enforcing the requirements of the regulation, we have learned that most commercial contracting methods result in a hospital's ability to identify and display as a dollar figure the payer-specific negotiated charges they have established with third party payers. For example, a negotiated rate is established as a dollar amount for an item or service or service package (that is, the 'base rate'), or is established as a percent discount off the gross charge for each item or service provided, or as a percentage of the Medicare rate which can be translated and displayed by the hospital as a standard dollar amount.

At other times, however, hospitals and payers establish the payer-specific negotiated charge by agreeing to an algorithm that will determine the dollar value of the allowed amount on a case-by-case basis after a pre-defined service package has been provided. This means that the standard charge that applies to the group of patients in a particular payer's plan can only prospectively be expressed as an algorithm, because the resulting allowed amount in dollars will be individualized on a case-by-case basis for a pre-defined service package, and thus cannot be known in advance or displayed as a rate that applies to each member of the group.

For example: Patients X and Y are under the same payer's plan. They both go to a hospital for the same procedure which is identified by the payer after analyzing the claim as having the same DRG code. The gross charges (that is, the charges billed on the claim to the payer) for each itemized item and service provided by the hospital for Patient X's procedure total $1,500, while Patient Y's gross charges for each itemized item and service provided by the hospital total $2,000. The hospital and payer have negotiated a payer-specific negotiated charge that is calculated as an amount equal to 50 percent off the total gross (or billed) charges for the procedure identified by the DRG code. The resulting charge (in dollars) for Patient X would be $750 while resulting charge (in dollars) for Patient Y would be $1,000. In this example, the payer-specific negotiated charge (as an algorithm) is the same for each patient in the payer's plan for the procedure, but it is possible that each patient covered under this payer's plan would have a different resulting charge, in dollars, for the same procedure. In other

[624] For additional discussion, please see the CY 2020 HPT final rule, 84 FR 65534.

[625] *https://www.cms.gov/files/document/nosurpriseactfactsheet-health-insurance-terms-you-should-know508c.pdf.*

words, in this example, there is no single dollar amount that would be appropriate for the hospital to post in its MRF as the payer-specific negotiated charge. Instead, the only payer-specific negotiated charge that applies to the group is the algorithm used to calculate the individualized dollar amount (in this example, the algorithm would be ''50 percent of the total gross charges'' that are billed on the claim for the procedure).

The reality of commercial healthcare contracting practices highlights a tension that sometimes exists between a hospital's establishment of a 'standard charge' that applies to a group of paying patients and the desire for individuals within the group to know and understand the specific cost of their care in dollars for specific hospital items or services. Currently, this tension is largely mitigated by price estimator tools that typically display 'estimated' dollar amounts that are based on past claims and, when available, knowledge of the contracting arrangements to predict, often with very high accuracy,[626] the most likely or expected allowed amount that will apply to an individual. When combined with the individual's insurance information, the individual's out-of-pocket can be determined and displayed. Therefore, as an alternative to leaving a 'blank' or 'N/A' in the MRF when no standard dollar amount is available, we allow hospitals to make public the standard algorithm that applies to the group. The publication of the algorithm makes it possible for a user of the file (such as a price estimator tool developer) to use that algorithm in conjunction with educated assumptions about the items or services likely to be utilized by a given patient for a given procedure, along with their corresponding gross charges, to estimate an allowed amount in dollars for the individual. This amount can be further personalized by including insurance information (such as the copay, co-insurance, or deductible) to determine the individual's estimated out-of-pocket dollar amount.

While we continue to support efforts via other methods, such as price estimator tools, for providing consumer-friendly and personalized out-of-pocket information, we have heard from interested parties that, when a hospital has negotiated a standard charge that can only be expressed as an algorithm, some estimate displayed in dollars within the MRF may be useful, particularly for making comparisons across hospitals. For example, an estimate displayed in dollars would permit users to make price comparisons across hospitals when, with respect to the same procedure and payer/plan, one hospital has established a payer-specific negotiated charge as an algorithm and a second as a dollar amount. We therefore considered whether and what data element could be required in the MRF to provide additional needed context for a payer-specific negotiated charge that is expressed as an algorithm.

We propose that when a hospital has established a payer-specific negotiated charge that can only be expressed as a percentage or algorithm, it must display alongside that percentage or algorithm a consumer-friendly 'expected allowed amount' in dollars for that payer/plan for that particular item or service. The 'expected allowed amount' would be the amount, on average, that the hospital estimates it will be paid for the item or service based on the contract with the third party payer. It is our understanding that hospitals often have such information already calculated and available as part of their revenue cycle management systems to provide a back-end check on their reimbursement from the third party payer, so we do not expect that the inclusion of such data in the MRF would represent a large burden. The 'consumer-friendly expected allowed amount' is likely to represent reimbursement for an average patient, rather than an exact amount, since, for a payer-specific negotiated charge based on an algorithm, the amount in dollars is known with certainty only after the patient has been discharged. As such, it is an estimate of the average amount that the hospital expects to receive for the item or service for all group members but not the final exact amount in dollars that would be actually apply to each group member. Even so, we believe this information would provide context to the public that is necessary to compare payer-specific negotiated charges across hospitals and a valuable benchmark against which price estimator tools can use to develop and estimate an individual's personalized out-of-pocket costs. We propose to add this consumer-friendly 'expected allowed amount' to the list of required data elements at § 180.50(b)(2).

(c) Proposals for Data Elements Related to Hospital Items and Services

At new § 180.50(b)(3), we propose that hospitals be required to provide standard charge information for additional data elements. These data would describe hospital items and services that correspond to the standard charges established by the hospital as follows:

- Recasting as a separate data element, but otherwise without change, the presently required description of the item or service and whether the standard charge is for an item or service provided in connection with an inpatient admission or an outpatient department visit.
- If a standard charge has been established for a drug, we propose that the hospital would be required to indicate the drug unit and type of measurement as separate data elements. We have seen hospital MRFs in which the drug unit and type of measurement are either not specified or are included in the same field as the description of the item or service. In the first case, when the drug unit and type of measurement is not specified, the user of the file has no basis for understanding the standard charge that the hospital has established. In other words, the description is not sufficient for the user to understand what quantity of the item or service the user would receive at the indicated standard charge amount. In the second case, when the drug unit and type of measurement are included in the same field as the description of the drug, the information is not easily machine-readable because computers are unable to parse the description if expressed as a 'string' of characters that are unique and undefined. Under this proposal, if the hospital has established a standard charge for a drug, the hospital would be required to encode the file with a description of the drug, including the applicable drug unit and type of measurement as a separate and distinct data element from the description. For example, if a hospital establishes a gross charge of $2 for an item or service it describes as 'aspirin 81mg chewable tablet—each', the hospital would be required to input data for each of the required separate data elements, which would look something like this in the MRF, based on the current technical specifications in the data dictionary that accompanies the currently available sample templates: gross charge: 2; description: aspirin 81mg chewable tablet; unit of measurement: 1; type of measurement: UN.[627] This indicates to the public that the standard charge established by the hospital for this item or service is $2.00 for a single tablet of

[626] Stults, et al. Assessment of Accuracy and Usability of a Fee Estimator for Ambulatory Care in an Integrated Health Care Delivery Network. JAMA Network Open. 2019;2(12):e1917445.

[627] Where ''UN'' in the sample format data dictionary (found here: *https://www.cms.gov/hospital-price-transparency/resources*) stands for ''unit'' which, in this example, comes in the form of a tablet.

a drug described as 'aspirin 81mg chewable tablet.'

We are aware that hospitals may at times establish standard charges for units of items and services other than drugs. While we would encourage hospitals to be transparent about such information in the MRF, we only propose to add data elements for the unit and type of measurement of drugs because the codes (such as HCPCS codes) for non-pharmaceutical items and services typically include instructions or additional descriptions that clarify the unit and type of measurement for the indicated item or service, but the codes (typically National Drug Codes (NDC)) used for pharmaceutical agents do not, and we do not believe it is necessary to burden the hospital with a requirement to publicly disclose information that is already available to the users of the file. Additionally, the TEP members discussed this issue and concluded that drugs are a unique class of items and service when it comes to a user's ability to clearly understand how hospitals are representing their standard charges. TEP members speculated that such challenges may arise because hospitals establish and display their standard charges for drugs using different methodologies. For example, it is often unclear in the hospital's MRF whether the payer-specific negotiated charge for a drug is based on the billing unit for the NDC associated with the drug or the billing unit associated with the drug's HCPCS code.

Based on our own experience in reviewing MRFs, we agree with the TEP members that more prescriptive requirements are necessary when it comes to display of standard charges for drugs and believe that requiring the drug unit and type of measurement as separate data elements would facilitate machine-readability and ensure clarity for the users of these files. We also agree with the TEP members that this proposal may introduce a burden on some hospitals that are already including such information in the description but would have to separate it for display in the CMS template. Because of this potential burden, we considered an alternative approach by which we would require the drug unit and type of measurement to be included in the description *or* encoded as separate data elements. This alternative would ensure availability of the data to users of the MRF, albeit in a way that would not be optimized for machine-readability. However, in this case we believe the burden on hospitals is outweighed by the need for improvements in data machine-readability, and therefore propose to require hospitals to report this information as separate data elements. We note that nothing would preclude the hospital from also including the information in its description of the drug. We seek comment on this proposal and the alternative we considered but are not proposing.

(d) Proposals for Data Elements Related to Item or Service Billing

At new § 180.50(b)(2)(iv), we propose to specify data elements related to item or service billing. We believe data elements related to item or service billing are necessary because the standard charges that a hospital establishes are often dependent on the way an item or service is billed. As such, including billing information may improve the public's understanding of the standard charge that has been established for the item or service. In specifying these data elements, we would retain, without modification, the current requirement that the MRF include any code used by the hospital for purposes of accounting or billing for the item or service (the example of such codes would be removed from the reg text as unnecessary). We propose to add a requirement that the hospital specify any relevant modifier(s) needed to describe the established standard charge, and the code type(s) (for example, whether the code is based on HCPCS, CPT, APC, DRG, NDC, revenue center, or other type of code). As discussed by the TEP members, there are instances where a hospital has established different standard charges for the same item or service description, depending on additional factors such as modifiers or revenue centers that are not included in the file. As such, TEP members agreed that some distinction to ensure meaningfulness of the standard charge would be helpful to users of the file and impose minimal hospital burden. Based on our experience in reviewing MRFs, we have also seen such instances and believe that requirements to include applicable codes that include modifiers and revenue center codes would help make necessary distinctions when multiple standard charges have been established for the same items or services. Separating the code itself (for example, the numbers of the code) from the code type (for example, ''HCPCS'') would directly improve machine-readability.

(e) Summary of Proposed Required Data Elements

In summary, we believe these proposed modifications to § 180.50(b) are necessary to improve hospitals' ability to display their standard charges in a more specific, clear, and standardized way. We believe the proposals would increase the meaningfulness of the standard charge information and heighten the public's ability to understand and more efficiently aggregate and use the data. Further, as described above, we believe these proposals would improve and streamline CMS's ability to enforce the HPT requirements.

Table 84 summarizes and compares the existing sample format data elements with the proposed data elements.

BILLING CODE 4120–01–P

TABLE 84: Data Elements Comparison Chart

Data Element	Included in Sample Template (Yes/No)?	Included in Proposal (Yes/No)?
File Date	Yes	Yes
File Version	Yes	Yes
Hospital Name	Yes	Yes
Hospital License	Yes	Yes
Hospital Location	Yes	Yes
Hospital Address	No	Yes
Hospital Financial Aid Policy	Yes	No
Gross Charges	Yes	Yes
Cash Discounted Price	Yes	Yes
Payer-Specific Negotiated Charges (by payer and plan; indicated as a dollar amount, percentage, or algorithm; type of contracting method)	Yes	Yes
Minimum and Maximum Deidentified Negotiated Charges	Yes	Yes
Consumer-Friendly Expected Allowed Amount	No	Yes
Item/Service Description	Yes	Yes
Billing/Accounting Codes, Modifiers, and Code Type	Yes	Yes
Billing Class	Yes	No
Setting (Inpatient or Outpatient)	Yes	Yes
Drug Unit and Type of Measurement	Yes	Yes

BILLING CODE 4120–01–C

We seek comment on these proposed revisions to § 180.50(b). Specifically, we seek comment on whether we should consider additional data elements to ensure the public's understanding and ability to meaningful use the standard charge information as displayed in hospital MRFs. In particular, we seek comment from hospitals related to display of payer-specific negotiated charges and solicit specific examples of complex contracting methodologies so that we can provide specific recommendations and technical instructions on display of standard charges resulting from such methodologies in the CMS template.

c. Proposals To Specify Formatting Requirements for Display of Standard Charge Information Using a CMS Template

In this section, we propose to require each hospital to conform to the CMS template layout, data specifications, data dictionary, and to meet any other specifications related to the encoding of the hospital's standard charge information in its MRF. We are making these proposals in order to improve automated aggregation of the standard charge information in the hospital's MRFs. Additionally, we believe these proposals will streamline our enforcement capabilities.

While most hospitals are ensuring that the data they display appears in a machine-readable format (such as JSON

or CSV), as required under the current regulation, many are not taking as much care to display the data that encodes the file in a way that improves machine-readability that facilitates automated aggregation of standard charge information. Even when individual hospitals make an effort to optimize the machine-readability of the data they include in the MRF, the lack of standardization in the MRF format data encoding limits the ability of users to aggregate MRF data in an automated way. This is because the format of the data encoded in the MRF is unknown to the user and therefore cannot be coded by them for further processing. This lack of standardization in format presents a barrier to intended use of the MRFs as expressed in the CY 2020 HPT final rule—that is, for enhancing the public's ability to use the data in, for example, consumer price estimator tools and in EHRs at the point of care for value-based referrals, or to aggregate and use the data to increase competition.

As indicated throughout the CY 2020 HPT final rule, we believed the flexibility that we initially afforded to hospitals was necessary to ensure that ''each hospital operating in the United States'' could implement the law and regulatory requirements. Now that hospitals have experience in making their standard charges public in an MRF and we have a better understanding of how hospitals establish their standard charges, we believe our data formatting requirements can be made more prescriptive to enhance the public's ability to use the hospital standard charge information to its fullest potential. These evolutionary changes may serve to decrease hospital burden.

To accomplish this, we propose to revise the introductory text at § 180.50(c) to require that each hospital must conform to the CMS template layout, data specifications, and data dictionary when making public the standard charge information required under paragraph (b).

Should these proposed rules be finalized, we propose to make at least one CMS template available to hospitals, and hospitals would be required to conform to its layout and comply with technical instructions (located in the template, corresponding data dictionary, and other technical guidance) to be published on a CMS website (such as the HPT website or CMS GitHub). A hospital's failure to display its standard charge information in the form and manner specified by CMS could lead to a compliance action. The CMS template and accompanying technical specifications would describe the form and manner in which the hospital must organize, arrange, and encode its standard charge information for the required data elements (if finalized, and as discussed in XVIII.B.3.b of this proposed rule) in its MRF.

For purposes of this requirement, we propose to make available a CMS template in CSV and JSON formats. Additionally, we propose to make available three different layouts. The three layouts would be similar to the three 'sample formats' that are currently available on the HPT website.[628] The three sample layout are: (1) JSON schema (plain format), (2) CSV (''wide'' format), and (3) CSV (''tall'' format). Although we considered proposing to require hospitals to display their standard charge information using only the JSON format, we concluded that some flexibility remains necessary given the variability in hospital sophistication and technical expertise, and the fact that these two proposed non-proprietary formats (CSV and JSON) appear to be the most frequently used by hospitals for displaying standard charges. We seek comment on this issue, and on whether we should instead require use of a single format (such as JSON).

Technical guidance, to which the hospital must conform for purposes of encoding the standard charge information, would be made available through, for example, a data dictionary and within the CMS template. The data dictionary would be similar to the data dictionary that CMS has developed for the 'sample templates,'[629] but would be updated to include any new policies that we finalize in the CY 2024 OPPS/ASC PPS final rule. This technical instruction would ensure consistent implementation and machine-readability of hospital MRFs across all hospitals. For example, CMS would provide guidance on how to conform to the CMS template layout and encode the data items for the required data elements; that guidance would also consist of the set of rules for the header and attribute naming and rules for allowed values for encoding standard charge information, including the data type (for example, enum, numeric, alphanumeric), data format (for example, string, float), and, in some cases, specific (''enum'') valid values (for example, ''inpatient'' ''outpatient'' ''both''). The data dictionary could also include a section on 'how to use the data dictionary' which would provide educational information about the encoding instructions for those with low technology expertise. We believe that providing such direction via separate technical instructions is reasonable because such direction does not rise to the meaningful substance that is subject to notice-and-comment rulemaking, and it would enable CMS to update such technical specifications to keep pace with and respond to technical developments and inquiries. Moreover, this proposal is consistent with data disclosure formatting requirements of other CMS programs such as the EHR Incentive Program (see 42 CFR 412.614).

Hospitals that do not conform to the CMS template layout, data specifications, and data dictionary would be determined to be noncompliant with 42 CFR 180.50(c) and could be subject to a compliance action. In addition to providing a data dictionary, to further aid hospitals, we are considering whether we should develop an MRF validator tool, similar to the validator tool provided by TIC on the CMS GitHub website.[630] The validator tool could be used by hospitals as a check for compliance with the formatting requirements of § 180.50(c), thereby providing some additional technical instruction and assurance that the formatting requirements have been met prior to posting the MRF online. We seek comment on whether hospitals would find a validator tool helpful and, if so, what technical specifications such a validator ought to assess.

We continue to encourage hospitals to provide any additional information they deem necessary to further explain or contextualize their standard charges, and we would provide technical instructions and specifications for hospitals to do so. For example, the data dictionary could include one or more optional data elements for inserting additional explanatory notes (similar to the ''additional generic notes'' data element included in the sample formats data dictionary), and could also permit hospitals to add other optional data elements such as 'average reimbursement amounts' derived from past claims, LAN designations, quality information, or the hospital's financial aid policy, or any other categories of information the hospital wishes to convey to the public related to hospital's standard charges.

Consistent with our proposal that hospitals must use a CSV or JSON format, we propose to remove the examples of specific types of machine-readable formats from the definition of ''machine-readable format'' at § 180.20.

[628] *https:/www.cms.gov/hospital-price-transparency/resources.*

[629] *https://www.cms.gov/hospital-price-transparency/resources.*

[630] *https://github.com/CMSgov/price-transparency-guide-validator.*

Similarly, we propose a technical edit to the naming convention at § 180.50(d)(5) to remove ''[json|xml|csv]'' and in its place add ''[json|csv].''

If the proposals related to these formatting requirements are finalized, CMS will provide additional technical instructions for how a hospital should indicate non-applicability, when necessary. As explained more fully in section XVIII.B.3.b of this proposed rule, we propose to apply the term 'as applicable' to the standard charge information that the hospital encodes in the MRF, and not to the data elements themselves. We continue to recognize that a hospital may have no applicable standard charge information to encode in some fields within a CMS template (this is particularly true for CSV formats, which can be opened in a human-readable spreadsheet format that forces column/row cross relationships between data elements which are not always applicable). We therefore reiterate that absence of encoded information does not necessarily mean that the MRF is incomplete. To illustrate using a specific example, a hospital may have established a gross charge for operating room time described as 'OR time, first 15 minutes' but may not have established any payer-specific negotiated charges that correspond to the same item or service. If the hospital has chosen to use the CMS CSV ''wide'' template (which can also be opened and viewed as a human-readable spreadsheet), a person may see that the cell at the intersection of the column 'gross charge' and row of 'OR time, first 15 minutes' would be encoded with the applicable standard charge amount but the cell at the intersection of any payer and plan's 'payer-specific negotiated charge' column(s) and the row of 'OR time, first 15 minutes' would be empty. In this example, the absence of encoded data would be a result of non-applicability, not non-compliance, because the hospital has not established a standard charge with the payers for a 15-minute increment of OR time.

We caution users of the files who choose to view MRFs in human-readable formats from concluding that a hospital is noncompliant solely based on blanks or the hospital's use of ''N/A'' (or other indicator(s) specified by CMS in guidance). To help mitigate ongoing misunderstandings by users of hospital MRF data, CMS intends to continue to educate the public on the standard charge information displayed by hospitals and proper interpretation of the information they contain. Additionally, as discussed in this proposed rule, we propose that hospitals include an affirmation of accuracy and completeness within the CMS template (see proposal in section XVIII.B.2.b of this proposed rule), which we believe would provide some assurance to users of hospital MRFs that the data is accurate and complete to the best of the hospital's knowledge and belief. Such an affirmation may also mitigate the need for a hospital to insert any indicator of non-applicability into its MRF. We are therefore not proposing to require insertion of such an indicator, although such indicators would not be precluded should a hospital wish to add them, so long as the hospital adheres to the technical specifications to preserve the machine-readability of the file. However, we seek comment on this issue. We seek comment on whether an indicator of non-applicability is necessary, whether such an indicator should be required or just recommended, and how CMS can best educate the public on the nature of standard charge information display, and, in particular, the potential for non-applicability in certain MRF formats.

Finally, if finalized, we propose a 60-day enforcement grace period for adoption and conformation to the new CMS template layout and encoding of standard charge information of the newly proposed data elements. To be clear, this proposal would be with respect solely to enforcement actions based on the new (if finalized) CMS template display requirements at revised § 180.50(b) and (c); it would in no way affect already-initiated compliance actions or actions for noncompliance with other requirements under part 180 as they are currently being implement. Additionally, this proposal would not apply to other proposals in this proposed rule which would become effective and enforced on January 1, 2024 including proposals related to inclusion of an affirmation statement in the hospital's MRF (discussed in section XVIII.B.2), the accessibility requirements as proposed and discussed in section XVIII.B.4 of this proposed rule, and any other proposals related to enforcement revisions discussed in section XVIII.C of this proposed rule. The effect of this proposal is that CMS would not begin to enforce any finalized requirement for hospitals to use the CMS template until 2 months after the effective date of the CY 2024 OPPS/ASC PPS final rule with comment period. We understand that some hospitals may have already adopted the sample format that CMS made available in November 2022, however, we propose to implement an enforcement grace period to accommodate hospitals that have adopted formats that vary significantly from the sample format. We seek comment on this proposal. In particular, we seek comment on whether and why an enforcement grace period should or should not be applied.

4. Proposal To Improve the Accessibility of Hospital MRFs

Currently, the HPT regulations at § 180.50(d) describe our requirements for the location and accessibility of the hospital's MRF. Specifically, the regulations require a hospital to select a publicly available website for purposes of making public its standard charges (§ 180.50(d)(1)) and displaying the standard charges information in a prominent manner and clearly identified with the hospital location with which the standard charge information is associated (§ 180.50(d)(2)). Additionally, at § 180.50(d)(3), the hospital must ensure that the standard charge information is easily accessible, without barriers, including, but not limited to, ensuring the information is accessible: free of charge; without having to establish a user account or password; without having to submit personal identifying information (PII); and to automated searches and direct file downloads through a link posted on a publicly available website. At § 180.50(d)(4), the digital file and the standard charge information contained within that file must be digitally searchable and, at § 180.50(d)(5), the file must use a naming convention specified by CMS.

As we explained in the CY 2020 HPT final rule, because of the flexibility we allowed to hospitals to choose the internet location, we recognized and expected that there would be some variability in how hospitals would choose to publicly display their MRF and how quickly the file could be found by the public. However, we indicated our belief that standardizing a file name or website location information could provide consumers with a standard pathway to find the information and would provide some uniformity, making it easier for potential software to review information on each website. We expressed our belief that specific requirements for file naming conventions and locations for posting on websites could also facilitate the monitoring and enforcement of the requirements.

We believe our current policies are sufficient for purposes of manual searches but may not be sufficient for automated searches. As we noted in the CY 2022 OPPS/ASC proposed rule, in our experience, many publicly available web pages that hospitals select to host

the MRF (or a link to the MRF) are discoverable using simple manual internet searches (using key words such as the hospital name plus 'standard charges,' 'price,' or 'machine-readable file') or, for example, by navigating to the hospital's home page and clicking and searching through pages related to patient billing and financing. However, despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, various MRF users, including IT developers and technology innovators, continue to express concerns that they can't efficiently, via automated techniques, aggregate the files. We believe these challenges should be addressed because we believe that ensuring that the MRFs and their data contents are easily accessible, including by members of the public who develop tools that improve the public's overall understanding and ability to use the information in meaningful ways, aligns with the MRFs' intended use. As we indicated in the CY 2020 HPT final rule, we believe that ''[b]y ensuring accessibility to all hospital standard charge data for all items and services, these data will be available for use by the public in price transparency tools, to be integrated into EHRs for purposes of clinical decision-making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare.''

As a result, we considered methods that would specifically improve the automated accessibility of MRFs. Thus, at proposed new § 180.50(d)(6), we propose to require that a hospital ensure that the public website it chooses to host the MRF establishes and maintains automated access to the MRF in two specific ways.

First, we propose, at new § 180.50(d)(6)(i) that the hospital ensure the public website includes a .txt file in the root folder that includes a standardized set of fields including the hospital location name that corresponds to the MRF, the source page URL that hosts the MRF, a direct link to the MRF (the MRF URL), and hospital point of contact information. CMS would make available the technical specifications for implementing this file in technical instructions, and could also consider creating a simple .txt generator tool to assist non-technical hospital personnel in generating a .txt file as well as plain-language instructions for complying with the requirement to post a .txt file to the root folder of the public website.

In considering this proposed approach to automating access to hospital MRFs, we identified several benefits, including: a standardized text file at a consistent location (for example, the root folder of the website) would provide automated tools a direct link to the MRF as opposed to the current approach of having to locate the correct web page within the website; technical experts suggest this is a relatively simple, low burden method that could be applied by maintainers of any public website that hosts the MRF; and information included in the .txt file could include information necessary to validate the contents of the file, for example, by including hospital point-of-contact information. We also considered potential drawbacks of this approach, including that any standardization of this nature is subject to errors in formatting which could negate the benefit to automated access and generate a compliance action. We believe the benefits outweigh the drawbacks for having a hospital ensure that the public website it chooses to host the MRF includes a .txt file in the root folder that includes a direct link to the MRF to establish and maintain automated access.

Second, we propose at new § 180.50(d)(6)(ii) that the hospital ensure the public website includes a link in the footer on its website, including but not limited to the homepage, that is labeled ''Hospital Price Transparency'' and links directly to the publicly available web page that hosts the link to the MRF. We propose this requirement because we believe the addition of standardized hyperlinks in the footer of hospital websites would aid in the automation of MRF data retrieval by creating a predictable navigation path to internal web pages that describe the HPT program and providing direct links to the MRF location. Once a human or web crawler arrives at the web page on which the MRF is located, it would be able to identify the specific location of the file(s) containing the pricing data. We believe that by making this information more easily accessible to automated searches and data aggregation, it would help third parties develop tools that further assist the public in understanding this information and capturing it in a meaningful way for making informed health care decisions. Moreover, we believe this requirement would be simple for hospitals to understand and implement, due to the website footer being a common place for hospitals to link to other information. In addition, using a standardized label for the link in the footer may make the location of the MRFs more visible to individual consumers manually searching for such files.

We seek comment on this proposed approach to improving accessibility of MRFs to automated searches. We particularly seek comment on whether there: may be better or more efficient ways of improving access to MRFs or the direct links to the MRFs; are additional benefits or challenges that we should alternatively consider; might be any challenges for automation tools to find MRFs when they are hosted by a publicly available website other than a website hosted by the hospital, and ways that would make those automated searches more easily accessible; and, might be any challenges for hospitals to meet the proposed requirements when the publicly available website hosting the MRF is not under direct control of the hospital. We also seek comment on whether the proposals to require use of a footer and .txt file, if finalized, are complementary to, or duplicative of, the requirements at § 180.50(d)(4) and (5) which, respectively, require that the digital file and standard charge information contained in that file must be digitally searchable; and that the file must use the naming convention specified by CMS at § 180.50(d)(5). We also seek comment on whether there is a better or more efficient standardized label for the link in the footer on the website, including but not limited to the homepage, that links directly to the publicly available website that hosts the link to the MRF.

C. Proposals To Improve and Enhance Enforcement

Section 2718(b)(3) of the PHS Act requires the Secretary to promulgate regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties. Our current monitoring and enforcement scheme is codified in our regulations at 45 CFR 180 subpart C. Section 180.70(a) states that CMS may monitor and assess hospital compliance with section 2718(e) of the PHS Act via methods including, but not limited to, evaluating complaints made by individuals or entities to CMS, reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. Should CMS conclude that a hospital is noncompliant with one or more of the requirements to make public standard charges, CMS may take any of the following actions described at § 180.70(b), which generally, but not necessarily, will occur in the following order:

- Provide a written warning notice to the hospital of the specific violation(s).

• Request a corrective action plan from the hospital if its noncompliance constitutes a material violation of one or more requirements.

• Impose a CMP on the hospital and publicize the penalty on a CMS website if the hospital fails to respond to CMS' request to submit a corrective action plan or comply with the requirements of a corrective action plan.

To better understand hospitals' HPT compliance and the impact of our implementation efforts, CMS conducted website assessments in 2021 and in 2022. CMS evaluated fourteen criteria for the MRF, and either eleven criteria for the shoppable services display or two criteria for the price estimator tool, depending upon which the hospital chose to offer. In the first 2 years of program implementation, our website assessments demonstrated a substantial increase in hospitals meeting website assessment criteria, increasing from 27 percent to 70 percent between 2021 and 2022.[631] Of the remainder of that 30 percent that failed to meet the criteria, 3 percent fully failed to meet website assessment criteria and 27 percent partially met website assessment criteria. Although these website assessments were not formal compliance reviews (which often require additional information from the hospital to make a final determination of compliance), we believe this demonstrates that hospitals are making improvements to come into compliance and that the increase is largely attributable to the increase in compliance penalties that went into effect in CY 2022, and our significant education, monitoring, and enforcement activities. We remain committed to ensuring compliance with our requirements and taking enforcement actions in areas of noncompliance.

Recently, we announced updates to our enforcement process[632] that are intended to increase the rates of HPT compliance. In this section, we make proposals that would further improve the efficiency, timeliness, and transparency of the compliance process.

1. Proposals for Improving Assessment of Hospital Compliance

At § 180.70(a), we finalized a process for monitoring hospital compliance with section 2718(e) of the PHS Act by which we may use monitoring efforts including, but not limited to, evaluating complaints made by individuals or entities to the CMS', reviewing individuals' or entities' analysis of noncompliance, and auditing hospitals' websites. The regulation text at § 180.70(a)(2) indicates that such methods are also used to 'assess' hospital compliance; however, we have found these methods to be more appropriate for monitoring, and not as appropriate or sufficient for assessing hospital compliance.

For example, a review of an MRF (such as is performed in a typical website assessment) may reveal some obvious deficiencies which can trigger a compliance action. Similarly, a complaint made by the public may be helpful in identifying an allegedly noncompliant hospital. While we appreciate and continue to encourage submission of complaints, there are many nuances and complexities associated with the way hospitals establish standard charges that can lead to questions related to, in particular, the accuracy and completeness of the standard charges information that is included in a hospital's MRF. By way of example, if a hospital's MRF does not include any 'discounted cash prices,' it can be difficult to determine whether the hospital is noncompliant with the requirement to disclose established discounted cash prices or whether the hospital has simply not established such charges and therefore has nothing to make public. Often, a hospital will preempt questions by making statements on its website or in the file to indicate when there is no applicable standard charges data to share with the public. But when such a public statement is absent, we find that it may be necessary for us to contact the hospital through our enforcement process to assess or determine whether the hospital is complying with the requirements of the regulation. In short, we have found it is necessary to employ methods beyond a simple audit of a hospital's website to definitively assess hospital compliance. We believe this distinction between monitoring and assessment activities is necessary because while monitoring activities can be used (by anyone, including CMS) to evaluate alleged noncompliance, only a formal CMS assessment can determine a hospital's compliance with the HPT requirements. We expect that many of these issues would be resolved if the proposed improvements to standardizing display of hospital standard charges (as discussed in section XVIII.B.3 of this proposed rule) are finalized as proposed. However, there could still be times when CMS would need additional information from the hospital to assess compliance.

We therefore propose to amend § 180.70(a)(2) to propose additional activities that CMS may use to monitor and assess for compliance. Specifically, we propose:

• To revise § 180.70(a)(2)(iii) to indicate that CMS may conduct a comprehensive compliance review of a hospital's standard charges information posted on a publicly available website. We believe this proposal is necessary to clarify the methods we may use to determine a hospital's compliance with HPT requirements.

• At new § 180.70(a)(2)(iv), requiring an authorized hospital official to submit to CMS a certification to the accuracy and completeness of the standard charges information posted in the MRF at any stage of the monitoring, assessment, or compliance phase. We also propose at new § 180.50(a)(3) that the hospital affirm within the MRF the accuracy and completeness of the standard charges information. However, we believe that this additional authority to require a formal certification by an authorized official is necessary to assist CMS in enforcement of the regulations when questions or complaints arise about the completeness or accuracy of the data. This certification authority is necessary because CMS may need a formal certification to resolve any specific questions related to the standard charges displayed and the items and services for which the hospital has established a standard charge, which might not be answered by the proposed affirmation statement in § 180.50(a)(3). For example, a formal certification may be necessary if a complainant alleges that specific standard charges displayed in the hospital's MRF are incomplete or inaccurate, or if certain items and services were provided by the hospital but are not displayed in the MRF with corresponding standard charges. Formal certification would provide assurance to CMS that the information within the MRF has been verified by the authorized official and is valid.

• At new § 180.70(a)(2)(v), requiring submission to CMS of additional documentation as may be necessary to assess hospital compliance. Such documentation may include contracting documentation to validate the standard charges the hospital displays, and verification of the hospital's licensure status or license number, in the event that information was not provided in the MRF. We believe that this proposal is necessary to enable CMS to adequately evaluate the hospital's publicly posted information to be able to assess compliance.

[631] *https://www.healthaffairs.org/content/forefront/hospital-price-transparency-progress-and-commitment-achieving-its-potential.*

[632] *https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates.*

Further, we propose two technical revisions. First, we propose a technical revision to the introductory text at § 180.70(a) so that it would read ''Monitoring and Assessment.'' Second, we propose to amend § 180.90 by revising paragraph (b)(2)(ii)(C) to remove the phrase ''resulting from monitoring activities'' and adding in its place the phrase ''resulting from monitoring and assessment activities.''

2. Proposal To Require Hospital Acknowledgement of Receipt of Warning Notice

Since the HPT regulations first became effective in January 2021, through June 2023, we have issued approximately 906 warning notices to hospitals. Though we send the compliance actions by tracked mail, a few hospitals have reported they did not receive the compliance action notifications. This causes delays in resolution of the deficiencies and in some cases resulted in additional compliance actions (for example, a request for a CAP) from CMS. Requiring that a hospital respond to CMS upon receipt of the warning notice will confirm receipt to CMS and hopefully prompt hospital personnel to appropriately route the warning notice to ensure timely corrective action.

We make clear that hospitals' internal process challenges do *not* (and in enforcement proceedings will not) excuse a hospital's HPT noncompliance. But, knowledge of this concern caused CMS to consider modifications to the compliance process for purposes of streamlining compliance activities and avoiding unnecessary re-reviews when a hospital has taken no action in response to a warning notice. Additionally, receiving confirmation of receipt directly from individuals at the organization responsible for resolving the deficiencies would streamline our enforcement by providing an appropriate compliance contact earlier in the enforcement process. We therefore propose at § 180.70(b)(1) that CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital. As part of the confirmation of receipt, we may request contact information from the hospital to streamline further communications.

3. Proposal for Actions To Address Noncompliance Within Hospital Systems

Section 2718(e) of the PHS Act and the HPT regulations apply to 'each hospital' operating in the U.S. As such, when CMS determines that a hospital is out of compliance with the regulations, CMS takes a compliance action against the individual hospital. Many hospitals, however, are part of a broader health system where common management officials have some degree of oversight and management over multiple hospitals. For example, some health systems have centralized administrative activities that establish standard charges for all the hospitals in the system, or that are responsible for ensuring compliance with Federal requirements. Under our current regulation, as explained in more detail in section XVIII.C.4 of this proposed rule, we have authority to disclose information about CMS compliance activity only when CMS issues a CMP, at which time CMS posts the CMP notice on its website. We believe that amending the regulation to provide CMS with express authority to notify health system officials of a compliance action that CMS has taken against one or more hospitals within their system, and working directly with them, where appropriate, to educate health system leadership and aid them in bringing all hospitals in the system into compliance, could aid in streamlining hospital compliance and our enforcement process.

Therefore, we propose to add new § 180.70(c) to state that, in the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b)) and the hospital is determined by CMS to be part of a health system, CMS may notify the health system leadership of the action and may work with hospital system leadership to address similar deficiencies for hospitals across the health system. In determining whether a hospital is part of a health system and health system contact information, we anticipate using data from sources including, but not limited to, internal CMS systems such as the Medicare Provider Enrollment, Chain, and Ownership System (PECOS) or the Chronic Conditions Data Warehouse (CCW). For example, PECOS may be used to identify relationships among organizations including ownership or enrollment associations.[633]

We believe that notifying health system officials of a compliance action taken against one of the hospitals in the system and working with health system officials and (where different) the hospital's officials to help the hospital to come into compliance would have several benefits. First, it could serve to ensure full and consistent compliance across all hospitals in the health system. Second, we believe the ability to work directly with health system officials, in addition to working with the noncompliant hospital, could reduce the need for compliance actions against other health system hospitals because the health system could more quickly and efficiently implement system-wide changes. For example, in one case multiple hospitals designated the same hospital system official as the point of contact to work with CMS. This allowed the hospital official to effectively correct violations cited across multiple locations and resulted in system-wide changes.

We seek comment on this proposal, including on whether there are additional data sources that CMS could access for purposes of identifying health system affiliation and leadership contact information.

4. Proposal To Publicize Compliance Actions and Outcomes

In the CY 2020 HPT final rule, we sought comment related to publicizing complaints and posting results of CMS assessments of hospitals' HPT compliance, including on the most effective way for CMS to publicize information regarding hospitals that fail to comply. Some commenters recommended publicizing noncompliant hospitals, while one commenter expressed the belief that publicizing noncompliance even after imposition of a CMP would amount to ''public shaming,'' which the commenter believed would not be of benefit. We considered these comments and ultimately finalized a policy at § 180.90(e)(1) that, should CMS issue a CMP to a hospital it determines is noncompliant, CMS would post the notice of imposition of the CMP on a CMS website.

In finalizing this policy, we explained that we believed that publicizing a hospital's noncompliance prior to imposing a CMP (for example) could be an effective tool to raise public awareness of, for example, incomplete hospital data, and could encourage hospitals to promptly remedy its violation(s) to avoid being publicly identified as noncompliant. However, we declined at the time to finalize publicizing information beyond publicizing the notice of imposition of a CMP. We indicated that we would consider revisiting through future rulemaking the timing for, and approach by, which CMS publicizes its

[633] Cohen GR, Jones DJ, Heeringa J, Barrett K, Furukawa MF, Miller D, Mutti A, Reschovsky JD, Machta R, Shortell SM, Fraze T, Rich E. Leveraging Diverse Data Sources to Identify and Describe U.S. Health Care Delivery Systems. EGEMS (Wash DC). 2017 Dec 15;5(3):9. doi: 10.5334/egems.200. PMID: 29881758; PMCID: PMC5983023.

determination of a hospital's noncompliance with the requirements to make public standard charges.

As of June 27, 2023, CMS had issued approximately 906 warning notices and 371 requests for CAPs since the initial regulation went into effect in January 2021. Approximately 301 hospitals were determined by CMS after a comprehensive compliance review to not require any compliance action and approximately 457 hospitals received a closure notice from CMS after having addressed deficiencies indicated in a prior warning notice or a request for a CAP following an initial comprehensive compliance review. We have imposed CMPs on four hospitals and publicized those CMP impositions on our website.[634] Every other hospital that we have identified as being noncompliant has either corrected its deficiencies or is cooperating with CMS to work towards correcting its deficiencies.

CMS routinely receives inquiries from the public, including state hospital associations, related to its compliance activities, asking, among other things, whether CMS has reviewed certain hospitals in certain states or other geographic locations. Given this significant public interest, we considered whether publicizing more information about CMS compliance activities and hospital-specific actions would be useful. We reviewed other federal programs that make public compliance actions for various programs, such as HHS/HRSA's 340B Drug Pricing Program which publicly posts audit results that include the name of the entity and state, audit findings, sanction, and corrective action status,[635] CMS' Part C and D results related to the Medicare Advantage and Prescription Drug Plan program audits[636] and compliance actions,[637] and the FDA which provides the public access to an online, searchable dashboard of compliance actions, including warning letters.[638]

We believe that such information could improve the public's understanding and transparency of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS. Additionally, making public compliance information may reduce repetitive complaints to CMS about hospital compliance issues and provide a central source of information for inquirers, including the media and state officials, who have expressed interest in this issue. Additionally, making these enforcement actions transparent may increase the likelihood that hospitals will more quickly come into compliance due to public scrutiny.

As a result, we propose at § 180.70(d) that CMS may publicize on its website information related to CMS' assessment of a hospital's compliance, any compliance actions taken against a hospital, the status of such compliance action(s), and the outcome of such compliance action(s). Additionally, we propose at § 180.70(d) that CMS may publicize on its website information related to notifications that CMS may send to health system leadership, if proposals discussed in section XVIII.C.3 of this proposed rule are finalized. Should CMS decide to publicize this information on its website, it would apply uniformly to all hospitals. We further note that, similar to other such assessments, the information we would make public would only be relevant as of the date indicated, and should not be taken to suggest any ongoing state of compliance or noncompliance.

D. Seeking Comment on Consumer-Friendly Displays and Alignment With Transparency in Coverage and No Surprises Act

As we concluded in the CY 2020 HPT final rule, transparency in pricing is necessary and can be effective to help bring down the cost of healthcare services, reduce price dispersion, and benefit consumers of healthcare services, including patients and employers. We discussed research suggesting that making consumer-friendly pricing information available to the public can reduce healthcare costs for consumers. We noted that despite the growing consumer demand and awareness of the need for healthcare pricing data, there continued to be a gap in easily accessible pricing information for consumers to use for healthcare shopping purposes. Specifically, there is inconsistent (and many times nonexistent) availability of provider charge information, among other limitations to understanding data made available or barriers to use of the data. We stated our belief that this information gap could, in part, be filled by the release of hospital standard charges as required by section 2718(e) of the PHS Act.

In response to comments, we acknowledged that there are additional barriers that must be overcome to allow consumers to identify appropriate sites of care for needed services, determine out-of-pocket costs in advance, and utilize indicators of quality of care to make value-based decisions. As we previously described in the CY 2020 HPT final rule, we stated our (continuing) belief that the HPT regulations requiring hospitals to make public standard charges are a necessary and important first step in ensuring transparency in healthcare prices for consumers, but that the release of hospital standard charge information is not sufficient by itself to achieve our ultimate goals for price transparency. We noted that HHS was continuing to explore other authorities to advance the Administration's goal of enhancing consumers' ability to choose the healthcare that is best for them, to make fully informed decisions about their healthcare, and to access both useful price and quality information. We also agreed with commenters that ''surprise billing'' was an issue of great concern to consumers and of great interest to both federal and state lawmakers. We noted that the HPT policies would not resolve that issue entirely, although we expressed our belief that it was possible that disclosure of hospital standard charges could help mitigate some consumer surprise billing (86 FR 65530).

As a result of comments indicating that long lists of standard charges might be difficult for the average person to directly use and understand, we considered ways that the authorities under section 2718(e) of the PHS Act could be used to require or encourage hospitals to make public standard charges for frequently provided services in a form and manner that might be more directly accessible and consumer-friendly. Ultimately, we finalized requirements for hospitals to display a list of payer-specific negotiated charges for a specified set and number of ''shoppable'' services as well as requirements intended to ensure the charge information for ''shoppable'' services would be presented in a way that is consumer-friendly, including presenting the information as a service package. We were also persuaded by commenters' suggestions that hospitals offering online price estimator tools that meet certain requirements including providing real-time individualized out-of-pocket cost estimates adequately satisfy our aim that hospitals communicate their standard charges in a consumer-friendly manner, and therefore deemed these price estimator tools as meeting our requirements for

[634] *https://www.cms.gov/hospital-price-transparency/enforcement-actions.*

[635] *https://www.hrsa.gov/opa/program-integrity/fy-22-audit-results.*

[636] *https://www.cms.gov/medicare/compliance-and-audits/part-c-and-part-d-compliance-and-audits/programaudits.*

[637] *https://www.cms.gov/Medicare/Compliance-and-Audits/Part-C-and-Part-D-Compliance-and-Audits/PartCandPartDComplianceActions.*

[638] *https://datadashboard.fda.gov/ora/cd/complianceactions.htm.*

making public standard charges for a limited set of shoppable services (84 FR 65579).

Since finalizing these policies, additional federal price transparency initiatives that rely on other authorities that more directly empower consumers with pricing information have been, or are in the process of being, implemented. Specifically, since publication of the CY 2020 HPT final rule in 2019, the Transparency in Coverage (TIC) rule (85 FR 72158, finalized in 2020)[639] and the No Surprises Act (NSA) (enacted as part of the Consolidation Appropriations Act of 2021) have been promulgated or enacted. Under the TIC final rules, with respect to plan years (in the individual market, policy years) beginning on or after January 1, 2023, most group health plans and issuers of group or individual health insurance coverage are required, among other requirements, to disclose personalized pricing information for covered items and service to their participants, beneficiaries, and enrollees through an online consumer tool, or in paper form, upon request. Cost estimates must be provided in real-time based on cost-sharing information that is accurate at the time of the request.[640] This requirement is being phased in over 2 years. An initial list of 500 shoppable services as determined by the DOL, HHS, and the Treasury (collectively, the Departments) will be required to be available via the internet based self-service tool for plan years that begin on or after January 1, 2023. The remainder of all items and services will be required to be available via these self-service tools for plan years that begin on or after January 1, 2024.

The NSA, which contains many provisions to protect consumers from surprise medical bills and to improve price transparency, will help patients understand health care costs in advance of care and to minimize unforeseen—or surprise—medical bills.[641] Section 9819 of the Internal Revenue Code (Code), section 719 of the Employee Retirement Income Security Act (ERISA), and section 2799A–4 of the PHS Act, as added by section 114 of division BB of the CAA, 2021, require group health plans and issuers of group or individual health insurance coverage to offer price comparison guidance by telephone and make available on the plan's or issuer's website a ''price comparison tool'' that (to the extent practicable) allows an individual enrolled under such plan or coverage, with respect to such plan year, such geographic region, and participating providers with respect to such plan or coverage, to compare the amount of cost-sharing that the individual would be responsible for paying under such plan or coverage with respect to the furnishing of a specific item or service by any such provider. In guidance issued on August 20, 2021, the Departments indicated that because the price comparison methods required by the CAA are largely duplicative of the internet-based self-service tool component of the TIC final rules, the Departments intend to propose rulemaking and seek public comment regarding whether compliance with the internet-based self-service tool requirements of the TIC Final Rules satisfies the analogous requirements set forth in section 9819 of the Code, section 719 of the ERISA, and section 2799A–4 of the PHS Act.[642]

Under section 2799B–6 of the PHS Act, as added by section 112 of title I of Division BB of the CAA, 2021, health care providers, health care facilities, and providers of air ambulance services are required to provide a good faith estimate (GFE) of expected charges for items and services to individuals who are not enrolled in a group health plan or group or individual health insurance coverage, Federal health care program, or Federal Employees Health Benefits (FEHB) program health benefits plan (uninsured individuals) or not seeking to file a claim with their group health plan, health insurance coverage, or FEHB health benefits plan (self-pay individuals). This GFE for uninsured (or self-pay) individuals must be provided in writing, either on paper or electronically (and may also be provided orally, if an uninsured (or self-pay) individual requests a good faith estimate in a method other than on paper or electronically), upon request or at the time of scheduling health care items and services.

On October 7, 2021, HHS issued regulations implementing section 2799B–6 of the PHS Act related to GFEs for uninsured (or self-pay) individuals at 45 CFR 149.610.[643] Under 45 CFR 149.610(b)(A) through (C), information regarding the availability of GFEs for uninsured (or self-pay) individuals must be written in a clear and understandable manner, prominently displayed (and easily searchable from a public search engine) on the convening provider's or convening facility's website, in the office, and on-site where scheduling or questions about the cost of items or services occur; orally provided when scheduling an item or service or when questions about the cost of items or services occur; and made available in accessible formats, and in the language(s) spoken by individual(s) considering or scheduling items or services with the convening provider or convening facility. At 45 CFR 149.610(c)(1), the content requirements of the GFE are outlined. The Departments have provided a sample of the GFE form online that includes the required information.[644]

For individuals who are enrolled in a group health plan or group or individual health insurance coverage, section 2799B–6 of the PHS Act requires providers and facilities to submit a GFE of expected charges to the covered individual's plan or issuer.[645] Section 9816(f) of the Code, section 716(f) of the ERISA, and section 2799A–1(f) of the PHS Act, as added by section 111 of title I of Division BB of the CAA, 2021, require plans and issuers, upon receiving the GFE, to send an advanced explanation of benefits (AEOB) in clear and understandable language to the covered individual, through mail or electronic means, as requested by the covered individual.[646] The AEOB must include the following information: (1) the network status of the provider or facility; (2) the contracted rate for the item or service, or, if the provider or facility is not a participating provider or facility, a description of how the covered individual can obtain information on providers and facilities that are participating; (3) the GFE received from the provider or facility; (4) a GFE of the amount the plan or coverage is responsible for paying; (5) the amount of any cost sharing which the covered individual would be responsible for paying with respect to the GFE received from the provider or

[639] *https://www.federalregister.gov/documents/2020/11/12/2020-24591/transparency-in-coverage.*

[640] *https://www.cms.gov/healthplan-price-transparency/plans-and-issuers.*

[641] *https://www.cms.gov/nosurprises.*

[642] FAQS about Affordable Care Act and Consolidated Appropriations Act, 2021 Implementation Part 49 (August 20, 2021), available at *https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs/Downloads/FAQs-Part-49.pdf.*

[643] Requirements Related to Surprise Billing; Part II, 86 FR 55980, 55983 (October 7, 2021), available at *https://www.govinfo.gov/content/pkg/FR-2021-10-07/pdf/2021-21441.pdf.*

[644] *https://www.cms.gov/files/document/good-faith-estimate-example.pdf.*

[645] The Department of Health and Human Services (HHS) interprets the requirements described in section 2799B–6 of the PHS Act apply to providers and facilities furnishing items or services to individuals covered by the Federal Employees Health Benefits (FEHB) Program in the same manner as for individuals enrolled in a group health plan or group or individual health insurance coverage.

[646] Pursuant to 5 U.S.C. 8902(p), FEHB carriers must comply with AEOB requirements in the same manner as those provisions apply to a group health plan or health insurance issuer offering group or individual health insurance coverage.

facility; (6) a GFE of the amount that the covered individual has incurred towards meeting the limit of the financial responsibility (including with respect to deductibles and out-of-pocket maximums) under the plan or coverage as of the date of the AEOB; and (7) disclaimers indicating whether coverage is subject to any medical management techniques (including concurrent review, prior authorization, and step-therapy or fail-first protocols). The AEOB must also indicate that the information provided is only an estimate based on the items and services reasonably expected to be furnished, at the time of scheduling (or requesting) the item or service, and is subject to change; and any other information or disclaimer the plan, issuer, or carrier determines is appropriate and that is consistent with information and disclaimers required under this section of the statute.

In September 2022, the Departments and the Office of Personnel Management (OPM) published a request for information to inform rulemaking on the provisions of the No Surprises Act related to the AEOB and GFE for covered individuals. (See 87 FR 56905.) [647] The RFI requested information and recommendations on transferring data from providers and facilities to plans, issuers, and carriers; other policy approaches; and the economic impacts of implementing these requirements. The Departments and OPM are carefully considering the public comments on the RFI as they, along with industry stakeholders, continue work toward developing the technical standards and policy framework necessary to support successful implementation of the AEOB and GFE for covered individuals.

As these new consumer-friendly requirements are in the process of becoming fully realized, we are interested in hearing from the public how the HPT requirements, in accord with the contours of the statutory authority conferred by section 2718(e) of the PHS Act, can best support and complement the consumer-friendly requirements found in these other price transparency initiatives. We particularly seek comment on:

- How, if at all, and consistent with its underlying legal authority, could the HPT consumer-friendly requirements at § 180.60 be revised to align with other price transparency initiatives?
- How aware are consumers about healthcare pricing information available from hospitals? We solicit recommendations on raising consumer awareness.
- What elements of health pricing information do you think consumers find most valuable in advance of receiving care? How do consumers currently access this pricing information? What are consumers' preferences for accessing this price information?
- Given the new requirements and authorities through TIC final rules and the NSA, respectively, is there still benefit to requiring hospitals to display their standard charges in a ''consumer-friendly'' manner under the HPT regulations?
- Within the contours of the statutory authority conferred by section 2718(e) of the PHS Act, should information in the hospital consumer-friendly display (including the information displayed in online price estimator tools) be revised to enhance alignment with price information provided under the TIC final rules and NSA regulations? If so, which data should be revised and how?
- How effective are hospital price estimator tools in providing consumers with actionable and personalized information? What is the minimum amount of personalized information that a consumer must provide for a price estimator tool to produce a personalized out-of-pocket estimate?
- How are third parties using MRF data to develop consumer-friendly pricing tools? What additional information is added by third parties to make standard charges consumer-friendly?
- Should we consider additional consumer-friendly requirements for future rulemaking, and to the extent our authorities permit? For example, what types of pricing information might give consumers the ability to compare the cost of healthcare services across healthcare providers? Is there an industry standard set of healthcare services or service packages that healthcare providers could use as a benchmark when establishing prices for consumers?

XIX. Proposed Changes to the Inpatient Prospective Payment System Medicare Code Editor

As discussed in the FY 2024 Inpatient Prospective Payment System (IPPS)/Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) proposed rule (88 FR 26752), the Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into a Medicare Severity Diagnosis Related Group (MS–DRG). If any of the MCE claim edits are triggered, the claim is returned to the provider to correct any issues related to the coded claims data and resubmit the claim for processing by the MAC.

After patient information is screened through the MCE and further development of the claim is conducted, the cases are classified into the appropriate MS–DRG by the Medicare GROUPER software program. The GROUPER program was developed as a means of classifying each case into an MS–DRG. The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS and therefore, also utilizes the MCE to identify cases that require further review before assignment into a Medicare Severity Long-Term Care Diagnosis Related Group (MS–LTC–DRG) can be made.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48874), we made available the FY 2023 ICD–10 MCE Version 40 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 40 (and ICD–10 MS–DRGs) are posted on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/ms-drg-classifications-and-software.* The MCE manual is currently comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26758) and prior rulemaking, as we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion, including with respect to whether there are concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to

[647] *https://www.govinfo.gov/content/pkg/FR-2022-09-16/pdf/2022-19798.pdf.*

assist in detecting errors or inaccuracies in the coded data. We note that historically, CMS has typically addressed the addition or deletion of MCE edits in its annual IPPS rulemakings, as well as the addition or deletion of ICD–10 diagnosis and procedure codes for the applicable MCE edit code lists effective October 1, consistent with the October 1 updates to the ICD–10 code set. We also note that currently, any changes applicable to the MCE edit code list in connection with the April 1 updates to the ICD–10 code set are made available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

As we have continued to evaluate the purpose and function of the MCE with respect to ICD–10, we recognize a need to further examine the operability of the MCE software program, including the current list of edits and the definitions of those edits. We have also considered the operation of the MCE as compared to the claims editing programs used for other Medicare payment systems, including how those edits are defined and applied, as well as how they are updated and maintained. For example, the Outpatient Prospective Payment System (OPPS) ''Integrated'' Outpatient Code Editor (I/OCE) is a software program that combines editing logic with an ambulatory payment classification (APC) assignment program. Similar to the IPPS MCE, the I/OCE edits the claims data to identify errors and ensure accuracy of submitted data. The I/OCE also serves additional claims editing functions as compared to the IPPS MCE. CMS makes updates to the I/OCE through quarterly releases with effective dates of January 1, April 1, July 1, and October 1 of each year. The updates reflect modifications to the program logic, such as additions and deletions of the ICD–10–CM diagnosis codes and Healthcare Common Procedure Coding System (HCPCS) codes, adding, removing or revising APCs, activating and deactivating edits, and other related actions. Changes and updates to the I/OCE are announced through quarterly I/OCE Change Requests (CRs) that are posted to the CMS website for MACs and public download at: *https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/OCEQtrReleaseSpecs.* The public may submit any questions or concerns related to the I/OCE through the CMS website at: *https://www.cms.gov/Medicare/Coding/OutpatientCodeEdit/ContactUs.*

Similar to the claims editing programs used for the OPPS and other Medicare payment systems, the claims edits under the MCE serve the operational function of identifying cases that require further review before classification into an MS–DRG. As previously discussed, if an edit is triggered, the claim is returned to the provider to correct any issues related to the coded claims data and to resubmit the claim for processing. Accordingly, consistent with the process that is used for updates to the I/OCE and other Medicare claims editing systems, we propose to address any future revisions to the MCE, including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. As described further in this section, we anticipate generally announcing any such changes or updates to the MCE as part of our instructions issued to the MACs in connection with the April 1 and October 1 ICD–10 code updates.

Under our current process, we announce updates to the MCE in connection with the April 1 and October 1 ICD–10 code updates, as applicable. For example, as discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26767), we issued Change Request (CR) 13034, Transmittal 11746, titled ''April 2023 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 40.1 for the International Classification of Diseases, Tenth Revision (ICD–10) Diagnosis Codes for Collection of Health-Related Social Needs (HRSNs) and New ICD–10 Procedure Coding System (PCS) Codes'', on December 15, 2022 (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11746cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 40.1, effective with discharges on and after April 1, 2023, reflecting the new diagnosis and procedure codes. We noted in the CR that the updated software, along with the updated ICD–10 MS–DRG V40.1 Definitions Manual and the Definitions of Medicare Code Edits V40.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* We issued similar instructions with respect to the October 1, 2022 updates to the MCE and related materials, including the release of the updated Version 40 ICD–10 MS–DRG GROUPER and Medicare Code Editor software, effective with discharges on and after October 1, 2022, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

Under our proposed approach, we would continue to issue instructions to the MACs in connection with any April 1 or October 1 updates to the IPPS MCE, including the effective date for the appropriate version of the MCE software program and the Definitions of Medicare Code Edits manual, and where these resources may be found on the CMS website. We would be interested in feedback as to whether it would also be helpful to list the specific MCE updates in the CR, including any additions or deletions of diagnosis or procedure codes or any addition or deletion of particular MCE edits. As previously noted, Chapter 2 of the MCE manual currently identifies the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. Beginning with the FY 2025 rulemaking, we would no longer address the addition or deletion of MCE edits or the addition or deletion of ICD–10 diagnosis and procedure codes for the applicable MCE edit code lists in the annual IPPS rulemakings.

We note that under this revised approach, we would also continue to welcome input from the public on the current edits, including input from providers and other users on how the MCE may currently be utilized in their respective workflow processes, as well as feedback on users' experience with the MCE, to inform any future revisions to the MCE.

We invite public comments on our proposal to remove discussion of the MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the MACs, as previously described.

XX. Proposed Technical Edits for REH Conditions of Participation and Critical Access Hospital (CAH) CoP Updates

On November 23, 2022, we published a final rule for the Rural Emergency Hospital health and safety standards (or the Conditions of Participation) titled, ''REH Conditions of Participation (CoP) and Critical Access Hospital (CAH) CoP Updates (CMS–3419–F)'', which was included in the ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for

Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19'' final rule with comment period (87 FR 71748). In that rule, we finalized the designation and certification for Rural Emergency Hospitals of part 485, subpart E, at 42 CFR 485.506. In the section titled, Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type, we noted the following:

> In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, section 1861(kkk)(3)(B) defines rural hospital as a subsection (d) hospital (as defined in section 1886(d)(1)(B) with not more than 50 beds located in a county (or equivalent unit of local government) in a rural area (as defined in section 1886(d)(2)(D) of the Act)), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act.''

We reiterated these requirements in the discussion of the Designation and Certification of REHs (§ 485.506) and finalized the regulatory text for the requirement at 42 CFR 485.506; however, we inadvertently cited the incorrect statutory references. We propose to correct these statutory citations from ''1881(d)(2)(D)'' to ''1886(d)(2)(D)'' and from ''1881(d)(1)(B)'' to ''1886(d)(1)(B)'' at § 485.506(b) and (c).

XXI. Rural Emergency Hospitals (REHs): Proposal Regarding Payment for Rural Emergency Hospitals (REHs)

A. Background on Rural Emergency Hospitals

The Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116–260), was signed into law on December 27, 2020. In this legislation, Congress established Rural Emergency Hospitals (REHs), a new rural Medicare provider type, to help maintain access to rural outpatient hospital services and prevent rural hospital closures. These providers furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals are eligible to convert to REHs if they were CAHs or rural hospitals with not more than 50 beds participating in Medicare as of the date of enactment of the CAA. For more information on the statutory authority for and the regulations implementing this new Medicare provider type, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72160 through 72161).

B. REH Payment Methodology

Pursuant to section 1834(x)(1) of the Act and CMS's implementing regulations at 42 CFR 419.91 and 419.92(a)(1), payment for REH services is defined in terms of the amount of payment ''that would otherwise apply under section 1833(t),'' for covered outpatient department (OPD) services, increased by 5 percent. As discussed in the CY 2023 OPPS/ASC final rule with comment period, CMS interprets ''rural emergency hospital services,'' as defined by section 1861(kkk)(1) of the Act, to include the scope of covered OPD services as defined in 1833(t)(1)(B) of the Act (excluding 1833(t)(1)(B)(ii) of the Act) (87 FR 72162). In the CY 2023 OPPS/ASC final rule with comment period, CMS also finalized regulations at 42 CFR 419.92(c) which address payment for services furnished by an REH that fall outside the scope of the covered OPD services under section 1833(t)(1)(B) of the Act. In addition, pursuant to section 1834(x)(2) of the Act, CMS codified at 42 CFR 419.92(b) that REHs will be paid an additional monthly facility payment, which was calculated for CY 2023 pursuant to the methodology described in the CY 2023 OPPS/ASC final rule with comment period and will be updated in subsequent years by the hospital market basket percentage increase as described in section 1886(b)(3)(B)(iii) of the Act.

C. Background on the IHS Outpatient All-Inclusive Rate (AIR) for Tribal and IHS Hospitals

For many years, tribal and IHS hospitals have been paid for hospital outpatient services furnished to Medicare beneficiaries based upon an outpatient per visit rate (the All-Inclusive Rate or ''AIR''), which is published annually by the IHS in the **Federal Register**. For additional information about the annual all-inclusive rates that IHS sets for inpatient and outpatient medical care provided by IHS facilities, please refer to IHS's CY 2023 Reimbursement Rate Notice which appeared in the **Federal Register** on February 27, 2023 (88 FR 12387).

In the CY 2002 OPPS final rule, CMS explicitly excluded IHS hospitals from the OPPS (66 FR at 59893) and codified that exclusion at § 419.20(b)(4), explaining that these facilities would continue to be paid under the separately established rate (the AIR) that is published annually in the **Federal Register**.

D. Proposal To Pay IHS and Tribal Hospitals That Convert to an REH Under the AIR

While some tribal and IHS hospitals have expressed interest in converting to an REH, they have expressed significant reservations about doing so due to having to transition from their existing payment methodology under the AIR to the REH payment methodology. As discussed above, in accordance with 42 CFR 419.20(b)(4) and CMS's longstanding policy, tribal and IHS hospitals are excluded from payment under the OPPS and instead are paid for hospital outpatient services under the AIR. In contrast, payment for REH services is defined in section 1834(x)(1) of the Act and under § 419.92(a)(1) as ''the amount of payment that would otherwise apply under section 1833(t) of the Act for the equivalent covered OPD service.'' Because there is no amount that would otherwise apply under section 1833(t) of the Act for hospital outpatient services furnished by tribal and IHS hospitals (because these hospitals have always been excluded from the OPPS for payment for hospital outpatient services), such services, when furnished by IHS operated or tribally operated REHs (hereinafter referred to as ''IHS–REHs''), do not fall within the scope of ''REH services.'' Under § 419.92(c), ''a service furnished by an REH that does not meet the definition of an REH service under § 419.91 is paid for under the payment system applicable to the service, provided the requirements for payment under that system are met.'' Consequently, we propose that IHS–REHs be paid for hospital outpatient services under the same rate (the applicable AIR that is established and published annually by the IHS) that would otherwise apply if these services were performed by an IHS or tribal hospital, consistent with the requirements of § 419.92(c). Under this proposal, the AIR would serve as payment for services furnished by IHS–REHs as part of an outpatient hospital encounter in the same manner as the AIR currently applies to IHS operated hospitals. Accordingly, to the extent that IHS hospitals are currently compensated via the AIR, rather than other Medicare payment mechanisms, for services other than hospital outpatient services that are furnished as part of an outpatient hospital encounter,

CMS is proposing that an IHS–REH would also be paid via the AIR when furnishing such services as part of an outpatient hospital encounter. Further, we note that existing beneficiary coinsurance policies applicable to such services under the AIR would remain unchanged by our proposal.

We propose that IHS–REHs would receive the REH monthly facility payment consistent with how this payment is made to REHs that are not tribally or IHS operated. CMS pays the monthly facility payment, pursuant to section 1834(x)(2) of the Act, as a separate payment to the REH that is not tied to specific services. Likewise, there is nothing in the statute and CMS's implementing regulations (42 CFR 419.92(b)) that would preclude REHs, including tribally or IHS operated REHs, from receiving this payment, even if they are paid under a separate payment framework for hospital outpatient services provided to beneficiaries (87 FR 72167 through 72181). Therefore, we propose that IHS–REHs would receive the monthly facility payment, consistent with § 419.92(b).

We also believe that for IHS–REHs it would be most efficient from a claims processing perspective for the IHS–REHs to process their claims separately from other REHs. Therefore, we propose to update the OPPS claims processing logic to include an IHS–REH specific payment flag, which an IHS–REH provider would utilize to indicate that the provider is an IHS–REH and should be paid the AIR.

Allowing tribal and IHS hospitals to continue receiving payment for hospital outpatient services through the AIR would remove several barriers to these hospitals converting to REHs. This proposal would provide tribal or IHS hospitals that convert to REHs greater predictability by allowing these facilities to continue to be paid via a familiar payment mechanism (the AIR), that will enable payment at the same rate that these hospitals are currently paid for outpatient hospital encounters. This proposal would also reduce the administrative burden for tribal and IHS hospitals to convert to an REH since they would already be familiar with reporting services and receiving payment using the AIR and would not need to invest in new software and additional staff training to receive payment for individual REH services at the REH payment rate. The continued use of the AIR would also make it easier for tribal and IHS providers that convert to an REH, but later determine it was the wrong decision for their facility, to convert back to a CAH or an inpatient hospital. Finally, CMS anticipates that this proposal would enable an increased number of rural tribal and IHS hospitals to attain an REH designation in a manner that would allow them to maintain their outpatient services, which may have a positive impact on health equity for Native Americans and people adversely affected by persistent poverty or inequality by facilitating access to health care in rural tribal communities.

We propose to add a new paragraph (d) to § 419.92 to codify that, beginning in CY 2024, IHS and tribally operated REHs, as defined in a proposed new paragraph (e) in § 419.92 as discussed below, will be paid under the outpatient hospital AIR that is established and published annually by the IHS instead of being paid the rates for REH services described in § 419.92(a)(1).

We also propose to amend § 419.93(a)(2), relating to services furnished by an off-campus provider-based department of an REH, to add a reference to the proposed new provision at § 419.92(d) for purposes of payment for services furnished by off-campus provider-based departments of IHS and tribally operated REHs.

Finally, we propose to establish a definition for IHS or tribally operated REHs, to identify the REHs that will be eligible to receive payment under the proposed new policy in § 419.92(d). Accordingly, we propose to add paragraph (e) to § 419.92 to codify that for purposes of § 419.92, an IHS or tribally operated REH means an REH, as defined in § 485.502, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

E. Exclusion of REHs From the OPPS

Hospitals that are excluded from payment under the OPPS are specified under § 419.20(b) of the regulations. Because, as described above, REHs are paid outside of the OPPS, we intended to revise § 419.20(b) during the CY 2023 rulemaking cycle to exclude REHs from payment under the OPPS. However, this intended revision was inadvertently omitted. Consequently, we are now proposing to codify the exclusion of REHs from the OPPS by adding new paragraph (5) to § 419.20(b).

XXII. Request for Public Comments on Potential Payment Under the IPPS and OPPS for Establishing and Maintaining Access to Essential Medicines

A. Overview

On January 26, 2021, President Biden issued Executive Order 14001, ''A Sustainable Public Health Supply Chain'' (86 FR 7219), which launched a whole-of-government effort to strengthen the resilience of medical supply chains, especially for pharmaceuticals and simple medical devices. This effort was bolstered subsequently by Executive Orders 14005, 14017, and 14081 (86 FR 7475, 11849, and 25711, respectively). In June 2021, as tasked in Executive Order 14017 on ''America's Supply Chains,'' the Department of Health and Human Services released a review of pharmaceuticals and active pharmaceutical ingredients, analyzing risks in these supply chains and recommending solutions to increase their reliability.[648] In July 2022, as tasked in Executive Order 14001, the Biden–Harris Administration also released the National Strategy for a Resilient Public Health Supply Chain, which laid out a roadmap to support reliable access to products for public health in the future, including through prevention and mitigation of medical product shortages.[649]

Over the last few years, shortages for critical medical products have persisted and continued to increase.[650] For pharmaceuticals, even before the COVID–19 pandemic, nearly two-thirds of hospitals reported more than 20 drug shortages at any one time—from antibiotics used to treat severe bacterial infections to crash cart drugs necessary to stabilize and resuscitate critically ill adults.[651] The frequency and severity of these supply disruptions has only been exacerbated over the last few years.

Recent data supports that hospitals are estimated to spend more than 8.6 million personnel hours and $360 million per year to address drug shortages, which will likely further result in treatment delays and denials, changes in treatment regimens,

[648] Department of Health and Human Services, Review of Pharmaceuticals and Active Pharmaceutical Ingredients (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[649] Department of Health and Human Services, National Strategy for a Resilient Public Health Supply Chain, July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[650] Senate Committee on Homeland Security & Governmental Affairs, Short Supply: The Health and National Security Risks of Drug Shortages, March 2023: *https://www.hsgac.senate.gov/wp-content/uploads/2023-06-06-HSGAC-Majority-Draft-Drug-Shortages-Report.-FINAL-CORRECTED.pdf.*

[651] Vizient, Drug Shortages and Labor Costs: Measuring the Hidden Costs of Drug Shortages on U.S. Hospitals, June 2019: *https://wieck-vizient-production.s3.us-west-1.amazonaws.com/page-Brum/attachment/c9dba646f40b9b5def8032480ea51e1e85194129.*

medication errors,[652] [653] [654] as well as higher rates of hospital-acquired infections and in-hospital mortality.[655] [656] The additional time, labor, and resources required to navigate drug shortages also increase health care costs.[657]

Hospitals' procurement preferences directly influence upstream intermediary and manufacturer behavior and can be leveraged to help foster a more resilient supply chain for lifesaving drugs and biologicals. With respect to shortages, supply chain resiliency includes having sufficient inventory that can be leveraged in the event of a supply disruption or demand increase—as opposed to ''just-in-time'' inventory-management efficiency that can leave supply chains vulnerable to shortage.[658] [659] This concept is especially true for essential medicines, which generally comprise of products that are medically necessary to have available at all times in an amount adequate to serve patient needs and in the appropriate dosage forms. A resilient supply can also include essential medicines from multiple manufacturers, including the availability of domestic pharmaceutical manufacturing capacity, to diversify the sourcing of essential medicines. We believe it is necessary to support practices that can curtail pharmaceutical shortages of essential medicines and promote resiliency in order to safeguard and improve the care hospitals are able to provide to beneficiaries.

We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under the IPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. This separate payment would not be budget neutral. An adjustment under the OPPS could be considered for future years.

B. Establishing and Maintaining a Buffer Stock of Essential Medicines

The report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment,* as developed by the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) prioritized 86 essential medicines (hereinafter referred to as, the ''essential medicines'') identified as either critical for minimum patient care in acute settings or important for acute care or important for acute care of respiratory illnesses/conditions, with no comparable alternative available. [660] [661] When hospitals have insufficient supply of these essential medicines, such as during a shortage, care for Medicare beneficiaries can be negatively impacted. To mitigate negative care outcomes in the event of insufficient supply, hospitals can adopt procurement strategies that foster a consistent, safe, stable, and resilient supply of these essential medicines. Such procurement strategies can include provisions to maintain or otherwise provide for extra stock of product (for example, either to maintain or to hold directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold), which can act as a buffer in the event of an unexpected increase in product use or disruption to supply. We expect that the resources required to establish and maintain access to a minimal ''buffer stock'' of essential medicines, such as a 3-month supply, will generally be greater than the resources required to establish and maintain access to these medicines through alternative means that are more susceptible to supply chain disruptions (for example, through so-called ''just-in-time'' inventory practices). Given these additional resource costs, we are considering separate payment under the IPPS for 2024, and the OPPS for future years, for the costs of establishing and maintaining access to a buffer stock of essential medicines.

For the IPPS for 2024 and subsequent years, the Secretary could potentially make this separate payment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines under section 1886(d)(5)(I) of the Act, which authorizes the Secretary to provide by regulation for such other exceptions and adjustments to the payment amounts under section 1886(d) of the Act as the Secretary deems appropriate.

For the OPPS, for future years, the Secretary could potentially make this separate payment for the additional resource costs under section 1833(t)(2)(E) of the Act. Section 1833(t)(2)(E) of the Act provides that the Secretary shall establish, in a budget neutral manner, other adjustments (in addition to outlier and transitional pass-through payments and payments for non-opioid treatments for pain relief) necessary to ensure equitable payments, such as adjustments for certain classes of hospitals.

Additionally, sustaining sources of domestically sourced medical supplies can also help support continued availability in the event of public health emergencies and other disruptions.[662] [663] This concept is consistent with our current policy for domestic National Institute for Occupational Safety and Health (NIOSH) approved surgical N95 respirators (87 FR 72037). Hospitals, as major purchasers and users in the U.S. of essential medicines, can support the existence of domestic sources by sourcing domestically made essential medicines. However, we expect that domestically manufactured essential medicines may be more expensive than those sourced from some other countries that may have lower manufacturing costs.[664] Given these additional resource

[652] American Journal of Health System Pharmacology, National Survey on the Effect of Oncology. Drug Shortages on Cancer Care, 2013: *https://pubmed.ncbi.nlm.nih.gov/23515514/.*

[653] JCO Oncology Practice, National Survey on the Effect of Oncology Drug Shortages in Clinical Practice, 2022: *https://pubmed.ncbi.nlm.nih.gov/35544740/.*

[654] Journal of the American Medical Association, Association between U.S. Norepinephrine Shortage and Mortality Among Patients with Septic Shock, 2017: *https://pubmed.ncbi.nlm.nih.gov/28322415/.*

[655] Clinical Infectious Diseases, The Effect of a Piperacillin/Tazobactam Shortage on Antimicrobial Prescribing and Clostridium difficile Risk in 88 US Medical Centers, 2017: *https://pubmed.ncbi.nlm.nih.gov/28444166/.*

[656] New England Journal of Medicine, The Impact of Drug Shortages on Children with Cancer: The Example of Mechlorethamine, 2012: *https://pubmed.ncbi.nlm.nih.gov/23268661/.*

[657] Department of Health and Human Services, ASPE Report to Congress: Impact of Drug Shortages on Consumer Costs, May 2023: *https://aspe.hhs.gov/reports/drug-shortages-impacts-consumer-costs.*

[658] Department of Health and Human Services, Review of Pharmaceuticals and Active Pharmaceutical Ingredients (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[659] Department of Health and Human Services, National Strategy for a Resilient Public Health Supply Chain, July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[660] *https://www.armiusa.org/wp-content/uploads/2022/07/ARMI_Essential-Medicines_Supply-Chain-Report_508.pdf.*

[661] *https://aspr.hhs.gov/newsroom/Pages/Essential-Medicines-May22.aspx.*

[662] Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

[663] Department of Health and Human Services, *National Strategy for a Resilient Public Health Supply Chain,* July 2021: *https://www.phe.gov/Preparedness/legal/Documents/National-Strategy-for-Resilient-Public-Health-Supply-Chain.pdf.*

[664] Department of Health and Human Services, *Review of Pharmaceuticals and Active Pharmaceutical Ingredients* (pp. 207–250), June 2021: *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf.*

costs, we took into account in developing the potential payment outlined in the previous paragraph (for the costs of establishing and maintaining access to a buffer stock of essential medicines) the increased costs to establish and maintain access to a buffer stock of domestically manufactured essential medicines.

In addition to essential medicines, we may consider expanding a potential Medicare payment policy in future years to include critical medical devices once the FDA's Critical Medical Device List (CMDL) becomes available. In accordance with implementation of Executive Order 14001 on a Sustainable Public Health Supply Chain, the FDA is leading an effort to develop this list of recommended medical devices that are critical to have on hand, at all times for patients, healthcare workers, and the U.S. public because of their clinical need. The list is expected to be available by the end of 2023.

C. Potential Separate Payment Under IPPS and OPPS for Establishing and Maintaining Access to a Buffer Stock of Essential Medicines

Currently, payment for the resources required to establish and maintain access to medically reasonable and necessary drugs and biologicals is generally part of the IPPS or OPPS payment. As noted in section XXII.B, we expect that the resources required to establish and maintain access to a buffer stock of essential medicines will generally be greater than the resources required to establish and maintain access to these medicines without such a buffer stock. Additionally, the resources required to establish and maintain access to a buffer stock of domestically manufactured essential medicines may generally be greater than the resources required to establish and maintain access to a buffer stock of these medicines from non-domestic sources. Given the policy goals discussed in sections XXII.A and XXII.B of this proposed rule, we believe it may be appropriate to pay separately for the additional resource costs associated with establishing and maintaining access, including through contractual arrangement, to a buffer stock of essential medicines. These potential separate payments would be in addition to payment for the essential medicines themselves, whether that payment is bundled with other items or services or the essential medicines are separately paid, and would help account for the additional resource costs associated with establishing and maintaining access, including through contractual arrangements, to a buffer stock of these essential medicines.

It is challenging to quantify these additional resource costs precisely based on currently available information. As noted in section XXII.B, hospitals could establish and maintain access to a buffer stock in a variety of ways, including, but not limited to, through contractual arrangements with distributors and wholesalers. Given the current challenge in precisely quantifying these additional resource costs, CMS could initially base the IPPS payment on the IPPS shares of the additional reasonable costs of a hospital to establish and maintain access to its buffer stock. The use of IPPS shares in this payment adjustment would be consistent with the use of these shares for the payment adjustment for domestic NIOSH approved surgical N95 respirators (87 FR 72037). These costs, which could include costs to hold essential medicines directly at the hospital, arrange contractually for a distributor to hold, or arrange contractually with a wholesaler for a manufacturer to hold, could be reported to CMS by a hospital in aggregate on its cost report. These costs would not include the costs of the essential medicine itself. This reported information, along with existing information already collected on the cost report, could be used to calculate a Medicare payment for the estimated cost, specific to each hospital, incurred to establish and maintain access to its buffer stock of these essential medicines. (As noted in section XXII.B, essential medicines refers to the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment.*) In accordance with the principles of reasonable cost as set forth in section 1861(v)(1)(A) of the Act and in 42 CFR 413.1 and 413.9, Medicare could make a lump-sum payment for Medicare's share of these additional inpatient costs at cost report settlement.

These payments for the IPPS shares of establishing and maintaining access to a buffer stock of essential medicines could be provided biweekly as interim lump-sum payments to the hospital and would be reconciled at cost report settlement. A provider could make a request for these biweekly interim lump sum payments for an applicable cost reporting period, as provided under 42 CFR 413.64 (Payments to providers: Specific rules) and 42 CFR 412.116(c) (Special interim payments for certain costs). These payment amounts would be determined by the Medicare Administrative Contractor (MAC), consistent with existing policies and procedures. In general, interim payments are determined by estimating the reimbursable amount for the year using Medicare principles of cost reimbursement and dividing it into 26 equal biweekly payments. The estimated amount is based on the most current cost data available, which will be reviewed and, if necessary, adjusted at least twice during the reporting period. (See CMS Pub 15–1 2405.2 for additional information.) The MACs could determine the interim lump-sum payments based on the data the hospital may provide that reflects the information that could be included on a supplemental cost reporting form. CMS will separately seek comment through the PRA process on a potential supplemental cost reporting form that could be used for this purpose. In future years, the MACs could determine the interim biweekly lump-sum payments utilizing information from the prior year's cost report, which may be adjusted based on the most current data available. This would be consistent with the current policies for medical education costs, and bad debts for uncollectible deductibles and coinsurance paid on interim biweekly basis as noted in CMS Pub 15–1 2405.2. It is also consistent with the payment adjustment for domestically sourced NIOSH approved surgical N95 respirators (87 FR 72037).

We are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS for the IPPS share of the reasonable costs of establishing and maintaining access to a 3-month buffer stock of one or more essential medicine(s). Essential medicines for the potential IPPS separate payment would be the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment.* An adjustment under OPPS could be considered for future years. We seek comment on all aspects of this potential payment policy.

If CMS were to finalize based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS, we are considering amending our regulations at 42 CFR 412.1 by revising paragraph (a)(1)(iv) to read as follows: ''(iv) Additional payments are made for outlier cases, bad debts, indirect medical education costs, for serving a disproportionate share of low-income patients, for the additional resource costs of domestic National Institute for Occupational Safety and Health approved surgical N95

respirators, and for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines.''

We are also considering amending our regulations, and seek comment on these potential revisions, at 42 CFR 412.2 by adding paragraph (f)(11) to read as follows: ''(11) A payment adjustment for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines as specified in § 412.113.''

We are also considering amending our regulations, and seek comment on these potential revisions, at § 412.113 by adding paragraph (g) to read as follows:

''(g) Additional resource costs of establishing and maintaining access to a buffer stock of essential medicines: (1) Essential medicines are the 86 medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* developed by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response and published in May of 2022. A buffer stock of essential medicines for a hospital is a 3-month supply of one or more essential medicines; (2) The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines for a hospital are the additional resource costs incurred by the hospital to directly hold a buffer stock of essential medicines for its patients, or arrange contractually for such a buffer stock to be held for use by the hospital for its patients. The additional resource costs of establishing and maintaining access to a buffer stock of essential medicines does not include the resource costs of the essential medicines themselves; (3) For cost reporting periods beginning on or after January 1, 2024, a payment adjustment to a hospital for the additional resource costs of establishing and maintaining access to a buffer stock of essential medicines is made as described in paragraph (g)(4) of this section; and (4) The payment adjustment is based on the reasonable cost incurred by the hospital for establishing and maintaining access to a buffer stock of essential medicines during the cost reporting period.''

D. Comment Solicitation on Additional Considerations

In addition to the potential payment policy as described in section XXII.C of this proposed rule, we also take particular interest, and seek comment on, the following. We note that we may consider amending, and finalizing, the potential policy under XXII.C of this proposed rule based on a review of the comments received on the following questions:

- How effective would this potential payment policy be at improving the resiliency of the supply chain for essential medicines and the care delivery system? How could it be improved, either initially or through future rulemaking? Are there suggested alternative pathways for establishing similar separate payments?
- The potential payment policy specified under section XXII.C of this proposed rule would account for any increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines compared to non-domestically manufactured ones. Even though the costs of essential medicines themselves is not considered a resource cost of establishing and maintaining access to a buffer stock, it is possible that there are additional resource costs, perhaps contractual, to establishing and maintaining access to a buffer stock of more expensive domestically manufactured essential medicines compared to non-domestically manufactured ones. What type of additional hospital resource costs are involved in establishing and maintaining access to domestically manufactured essential medicines compared to non-domestically manufactured ones? Are there alternative approaches that might better recognize the increased resource costs for a hospital to establish and maintain access to a buffer stock of domestically manufactured essential medicines? How might any suggested alternatives be better at improving the resiliency of the supply chain for essential medicines and the care delivery system? What standard should be used to define domestic manufacturing for suggested alternatives? Specifically, would the international trade rule of ''substantial transformation'' be appropriate to define domestic manufacturing, if that product was substantially transformed in the U.S.? Would hospitals have sufficient access to that information when making procurement decisions or doing reporting to CMS?
- Are the 86 essential medicines prioritized in the report *Essential Medicines Supply Chain and Manufacturing Resilience Assessment* the appropriate initial list of essential medicines for this potential payment policy? How often should HHS consider updating the respective list used for establishing these potential additional payments? For example, HHS expects it may update the essential medicine list every two years. Should that be the frequency for purposes of administering these additional payments? Also, what additional criteria should be considered when determining whether the list should be updated?
- Should HHS consider expanding the list of essential medicines used in establishing these potential additional payments to include essential medicines used in the treatment of cancer?
- Is a 3-month supply the appropriate amount of supply for the buffer stock or should an alternative duration be used? We recognize that a 3-month supply may not be feasible in all circumstances, given various factors, including, but not limited to, the shelf life of certain essential medicines. What additional considerations, if any, are needed?
- In general, how much of a buffer stock of these essential medicines are hospitals currently maintaining across different hospital types and regions (whether directly, or contractually through distributors or other partners)? Are there unique circumstances for safety net hospitals that should be taken into consideration in any potential payment policy?
- What type of additional hospital resource costs are involved in establishing and maintaining access to a buffer stock of essential medicines? To what degree, and under what circumstances, might hospitals use contractual arrangements? What type of contractual arrangements might be used?
- What flexibilities should exist for implementing buffer stock practices?
- What immediate impacts on the supply of essential medicines could be expected upon implementation of this potential policy? What steps, if any, would need to be taken to mitigate risks of possible demand-driven shortages as a result of implementation of such a policy?
- While the availability of essential medicines is critical at all times, it is especially the case for emergencies. Should there be a separate payment adjustment to more acutely address supply issues that emerge specific to the case of preparedness as a pandemic or other public health emergency emerges?
- How should such a policy be considered for essential medicines that are currently in shortage, and thus potentially not appropriate for arranging to have buffer stock? What steps, if any, would need to be taken if an eligible essential medicine enters shortage while such a policy is in place?
- Should critical medical devices be considered in future rulemaking for inclusion in a potential payment policy?

++ Which types of medical devices do hospitals currently maintain in a buffer stock?

++ Do single use devices (including consumables) or reusable devices pose a greater risk of supply chain impact leading to shortages?

++ Are hospitals more likely to have a buffer stock of devices that are single use (including consumables) or reusable?

++ What levels of buffer stock do hospitals currently keep on hand for devices they consider critical?

++ Is the quantity of buffer stock dependent on type of medical device (single use vs. reusable)?

++ Generally, how many days of buffer stock is typically carried by device type?

++ What other factors are considered when determining which types of medical devices to maintain in a buffer stock?

+ What are the prevailing buffer stock strategies employed across deice types (*e.g.,* just in time, consignment, single warehousing, warehouse to warehouse)?

XXIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Copayment Capped at the Inpatient Deductible of $1,364.00'' where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2024 and subsequent years, we propose to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled ''Drug Pass-Through Expiration during Calendar Year'' to include devices, so that the column reads: ''Drug and Device Pass-Through Expiration during Calendar Year'' where we flagged, through the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2024 and subsequent years, we propose to retain these columns that are updated to reflect the devices for which pass-through payment is expiring in the applicable year.

In addition, we propose to delete the column titled ''Copayment Capped at the Inpatient Deductible'' and instead to add a new column for ''Adjusted Beneficiary Copayment'' to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also propose to add another column for notes. We propose that the ''Note'' column would contain multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

To view the Addenda to this proposed rule pertaining to proposed CY 2024 payments under the OPPS, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Hospital-Outpatient-Regulations-and-Notices.html;* select ''CMS–1786–P'' from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled ''2024 NPRM OPPS Addenda'' in the related links section at the bottom of the page. To view the Addenda to the CY 2024 OPPS/ASC proposed rule pertaining to CY 2024 payments under the ASC payment system, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices.html;* select ''CMS–1786–P'' from the list of regulations. The ASC Addenda to the CY 2024 OPPS/ASC proposed rule are contained in a zipped folder titled ''2024 NPRM Addendum AA, BB, DD1, DD2, EE, and FF'' in the related links section at the bottom of the page.

XXIV. 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 Related to Proposed Intensive Outpatient Physician Certification Requirements

As discussed in section VIII.B.3 of this proposed rule, we propose to codify the content of certification and plan of treatment requirements for intensive outpatient services at § 424.24(d). Specifically, we propose to mirror the PHP content of certification and plan of care treatment requirements at § 424.24(e), with the following exceptions: require the content of certification to include documentation that the individual requires such services for a minimum of 9 hours per week (with no requirement for a need for inpatient psychiatric care if the IOP services were not provided).

The proposed ICRs at § 424.24(d) are subject to the Act. However, we believe the burden associated with these ICRs are exempt, as defined by 5 CFR 1320.3(b)(2), because the time, effort, and financial resources necessary to comply with these requirements would be incurred by persons in the normal course of their activities. We believe the record keeping requirements described in section VIII.B.3 of this proposed rule are a usual and customary part of physicians' activities in developing the plan of treatment for existing patients in intensive outpatient programs, and that the requirements are similar to existing ICRs under Medicare for partial hospitalization patients.

B. ICRs Related to the Hospital OQR Program

1. Background

The Hospital Outpatient Quality Reporting (OQR) Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2011 through CY 2023 OPPS/ASC final rules (75 FR 72111 through 72114; 76 FR 74549 through 74554; 77 FR 68527 through 68532; 78 FR 75170 through 75172; 79 FR 67012 through 67015; 80 FR 70580 through 70582; 81 FR 79862 through 79863; 82 FR 59476 through 59479; 83 FR 59155 through 59156; 84 FR 61468 through 61469; 85 FR 86266 through 86267; 86 FR 63961 through 63968, and 87 FR 72250 through 72252, respectively) for detailed discussions of the previously finalized Hospital OQR Program ICRs. The ICRs associated with the Hospital OQR Program are currently approved under OMB control number 0938–1109, which expires on February 28, 2025. In the CY 2023 OPPS/ASC final rule, our burden estimates were based on an assumption that approximately 3,350 hospitals would report data to the Hospital OQR Program. For this proposed rule, based on data from the CY 2023 Hospital OQR Program payment determination, which supports this assumption, we will continue to estimate that 3,350 hospitals will report data to the Hospital OQR Program, unless otherwise noted. While the exact number of hospitals required to submit data annually may vary, we use this estimate to be consistent with previous rules and for ease of calculation across reporting periods.

In the CY 2018 OPPS/ASC final rule (82 FR 52617), we finalized a policy to utilize the median hourly wage rate for Medical Records and Health Information Technicians, in accordance with the Bureau of Labor Statistics (BLS), to calculate our burden estimates for the Hospital OQR Program. We note that since the CY 2023 OPPS/ASC final rule, BLS removed this labor category and added a new labor category titled ''Medical Records Specialists.'' While the most recent data from the BLS reflects a median hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the hourly mean wage for ''general medical and surgical hospitals,''[665] which is an industry within medical records specialists. We believe the industry of ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than other industries that fall under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

In section XIV.B.2 of this proposed rule, we propose to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We propose to adopt three new measures: (1) Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting, beginning with the voluntary CYs 2025 and 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (2) the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM), beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (3) readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure with modification, with voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. We are also proposing to remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

2. Information Collection Burden for the Proposal To Modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPS/ASC final rule, we finalized adoption of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the Hospital OQR Program (87 FR 71748 through 72310). In section XIV.B.2.a of this proposed rule, we propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the timeframes within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the CY 2024 reporting period/CY 2026 payment determination for the Hospital OQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPS/ASC final rule (86 FR 63962).

We do not believe that the use of the term ''up to date'' or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we are not proposing any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this proposal. The modified COVID–19 Vaccination Coverage Among HCP measure would continue to be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA) (Pub. L. 99–660).

3. Information Collection Burden for the Proposal To Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning With the CY 2024 Reporting Period

In the CY 2014 OPPS/ASC final rule (78 FR 75102 through 75104), we

[665] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery beginning with the CY 2016 payment determination; this measure currently is voluntary. In section XIV.B.2.b of this proposed rule, we propose to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being proposed are currently allowable for collecting data for this measure, we do not believe limiting use to these three surveys would result in a change in burden. As a result, we are not proposing any changes in burden per response associated with this proposal. Additionally, as currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900.[666] We are not proposing an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this proposal.

4. Information Collection Burden for the Proposal To Modify the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPS/ASC final rule, we finalized the Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75101 through 75102). In section XIV.B.2.c of this proposed rule, we propose to amend the measure denominator language by removing the phrase ''aged 50 years'' and adding in its place the phrase ''aged 45 years.''

As currently stated in the Hospital OQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for hospitals with an outpatient population size of between 0 and 900 and 96 cases for hospitals with an outpatient population size of greater than 900. We are not proposing an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this proposal.

5. Information Collection Burden for the Proposal To Adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting Beginning With Voluntary CYs 2025 and 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

In section XIV.B.3.b of this proposed rule, we propose to adopt the THA/TKA PRO–PM beginning with voluntary CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the Hospital Quality Reporting (HQR) system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the Hospital OQR Program.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we are not proposing to require how hospitals collect PRO data for this measure, hospitals collecting PRO data would have multiple options for when and how they would collect these data so they could best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that can occur in an office or at the hospital. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection can occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection could include completion of the post-operative survey using email, mail, telephone, or through a patient portal. Similar to other surveys, like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes would maximize response rates as it allows for different patient preferences.

For the THA/TKA PRO–PM data, hospitals would be able to submit data during two voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with CY 2026 for eligible procedures occurring between January 1, 2026 through December 31, 2026. Voluntary reporting would be followed by mandatory reporting for eligible elective procedures beginning with the CY 2027 reporting period (occurring January 1, 2027 through December 31, 2027), impacting the CY 2030 payment determination. Hospitals would need to submit data twice (pre-operative data and post-operative data).

For the purposes of calculating burden, similar to assumptions used for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 through 49387), we estimate that during the voluntary periods, 50 percent of hospitals that perform at least one THA/TKA procedure would submit data for 50 percent of THA/TKA patients. For purposes of calculating burden, we estimate that, during the mandatory period, hospitals would submit for 100 percent of patients. While we propose to require hospitals to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case hospitals exceed this threshold.

To estimate the cost burden for patients completing the surveys for this proposed measure, we refer to the ''Valuing Time in U.S. Department of

[666] *https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf.*

Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' as it identifies the approach for valuing time when individuals undertake activities on their own time.[667] Therefore, we estimate that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hour. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hour. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

For burden estimating purposes for this proposed measure, we assume that most hospitals would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 526,793 THA/TKA procedures occur in the outpatient setting each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For CY 2025 and CY 2026 reporting periods, we assume 131,698 patients would complete the survey (526,793 patients × 0.50 × 0.50 of hospitals) for a total of 15,914 hours annually (131,698 respondents × 0.120833 hours) at a cost of $329,579 (15,914 hours × $20.71) across all hospitals. Beginning with mandatory reporting in the CY 2027 reporting period, we estimate a total of 63,654 hours (526,793 patients × 0.120833 hours) at a cost of $1,318,274 (63,654 hours × $20.71) across all hospitals.

Regarding hospitals' burden related to submitting data for this proposed measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. Hospitals would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the initial voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each reporting period, we estimate that each hospital would spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data. For the voluntary CY 2026 reporting period, we estimate a burden for all participating hospitals of 279.2 hours (0.167 hours × 3,350 hospitals × 50 percent) at a cost of $14,552 (279.2 hours × $52.12). For the voluntary CY 2027 reporting period, we estimate a burden for all participating hospitals of 558.3 hours (0.33 hours × 3,350 hospitals × 50 percent) at a cost of $29,099 (558.3 hours × $52.12). For the mandatory CY 2028 reporting period, we estimate a burden for all participating hospitals of 837.5 hours [(0.167 hours × 3,350 hospitals × 50 percent) + (0.167 hours × 3,350 hospitals)] at a cost of $43,651 (837.5 hours × $52.12). For the mandatory CY 2029 reporting period and subsequent years, we estimate a total of 1,116.7 hours (0.33 hours × 3,350 hospitals) at a cost of $58,202 (1,116.7 hours × $52.12).

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.3.b ''Regulatory Impact Analysis'' of this proposed rule.

6. Information Collection Burden for the Proposal To Adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) eCQM, Beginning With the Voluntary CY 2025 Reporting Period, followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3.c of this proposed rule, we propose to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM, beginning with the voluntary CY 2025 reporting period, followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. For the CY 2025 voluntary reporting period, hospitals would be able to voluntarily report the measure for one or more quarters during the year. For subsequent years, as described in section XIV.E.6.b of this proposed rule, we propose to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with two self-selected quarters for the CY 2026 reporting period/CY 2028 payment determination, and all four quarters for the CY 2027 reporting period/CY 2029 payment determination.

For the voluntary reporting period in CY 2025, we estimate 20 percent of hospitals would voluntarily report at least one quarter of data for the measure with 100 percent of hospitals reporting the measure as proposed to be required in subsequent years. Similar to the ST-elevation myocardial infarction (STEMI) eCQM for which adoption was finalized in the CY 2022 OPPS/ASC final rule for the Hospital OQR Program, we assume a Medical Records Specialist would require 10 minutes to submit the data required per quarter for each hospital (86 FR 63962 through 63963). For the CY 2025 voluntary reporting period, we estimate an annual burden for all participating hospitals of 111.7 hours (3,350 hospitals × 20 percent × 0.1667 hours × 1 quarter) at a cost of $5,822 (111.7 hours × $52.12). For the CY 2026 reporting period/CY 2028 payment determination, we estimate the annual burden for all participating hospitals to be 1,116.7 hours (3,350 hospitals × .1667 hours × 2 quarters) at a cost of $58,202 (1,116.7 hours × $52.12). For the CY 2027 reporting period/CY 2029 payment determination, we estimate the annual burden for all participating hospitals to be 2,233.3 hours (3,350 hospitals × .1667 hours × 4 quarters) at a cost of $116,400 (2,233.3 hours × $52.12).

7. Information Collection Burden for the Proposal To Re-Adopt With Modification the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures Measure, Beginning With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XIV.B.3.a of this proposed rule, we propose to re-adopt with modification the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures measure, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. This measure was previously finalized in the CY 2012 OPPS/ASC final rule

[667] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

with the assumption that, because hospitals must determine their populations for data reporting purposes—and most hospitals are voluntarily reporting population and sampling data for Hospital OQR Program purposes—the only additional burden would be the reporting of the data using a web-based tool (now the HQR system) (76 FR 74552 through 74553). This assumption continues to be applicable; therefore, we estimate the burden to be consistent with both the CY 2012 OPPS/ASC final rule when the measure was initially adopted (76 FR 74552) and with the CY 2018 OPPS/ASC final rule when the measure was previously removed (82 FR 52618). We estimate that each participating hospital would spend 10 minutes per year to collect and submit the data for this measure. For the voluntary CY 2025 reporting period, we assume 20 percent of hospitals will report data, resulting in an annual burden of 111.7 hours (3,350 hospitals × 20 percent × 0.167 hours) at a cost of $5,822 (111.7 hours × $52.12). For mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, we estimate an annual burden of 558.3 hours (3,350 hospitals × 0.167 hours) at a cost of $29,099 (558.3 hours × $52.12).

8. Information Collection Burden for the Proposal To Remove the Left Without Being Seen Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In section XIV.B.1.a of this proposed rule, we proposed to remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination. Under OMB control number 0938–1109 (expiration date February 28, 2025), the currently approved burden for this measure is estimated to be 10 minutes (0.1667 hours) per hospital to report measure data via a web-based tool located on a CMS website.[668] In addition, as stated under OMB control number 0938–1109, there is no additional burden for abstraction of chart data associated with this measure. Therefore, we estimate the decrease in burden associated with the removal of this measure to be 558.3 hours (0.1667 hours × 3,350 hospitals) at a cost of $29,100 (558.3 hours × $52.12/hour).

9. Summary of Information Collection Burden Estimates for the Hospital OQR Program

In summary, under OMB control number 0938–1109 (expiration date February 28, 2025), we estimate that the proposals in this proposed rule would result in an increase of 67,004 hours at a cost of $1,492,875 for 3,350 OPPS hospitals across a 6-year period from the CY 2024 reporting period/CY 2026 payment determination through the CY 2029 reporting period/CY 2030 payment determination. The following Tables 85 through 90 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2030 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1109.

BILLING CODE 4120–01–P

TABLE 85: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/CY 2026 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
	Total Change in Information Collection Burden Hours: -558.3							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-558.3) = **-$29,100**							

[668] CY 2023 Final Rule Hospital OQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/DownloadDocument?objectID=129107500.*

TABLE 86: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Add Excessive Radiation eCQM	10	1	670	1	0.167	111.7	N/A	+111.7
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	670	1	0.167	111.7	N/A	+111.7
	Total Change in Information Collection Burden Hours: +15,579							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+15,579) = **$312,123**							

TABLE 87: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	1,675	78.6	9.5	15,914	N/A	+15,914
Add THA/TKA PRO-PM (Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Add Excessive Radiation eCQM	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
	Total Change in Information Collection Burden Hours: +17,310							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+17,310) = **$402,332**							

TABLE 88: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	1,675	1	0.33	558.3	N/A	+558.3
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
	Total Change in Information Collection Burden Hours: +66,446							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,446) = **$1,463,772**							

TABLE 89: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survcy Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Voluntary Data Submission)	10	1	1,675	1	0.167	279.2	N/A	+279.2
Add THA/TKA PRO-PM (Mandatory Data Submission)	10	1	3,350	1	0.167	558.3	N/A	+558.3
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
	Total Change in Information Collection Burden Hours: +66,725							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+66,725) = **$1,478,324**							

TABLE 90: SUMMARY OF HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS hospitals reporting**	**Average number records per hospital per quarter**	**Annual burden (hours) per hospital**	**Proposed annual burden (hours) across OPPS hospitals**	**Previously finalized annual burden (hours) across OPPS hospitals**	**Net difference in annual burden hours**
Remove Left Without Being Seen measure	-10	1	3,350	1	0.167	0	558.3	-558.3
Add THA/TKA PRO-PM (Survey Completion)	3.625	2	3,350	157.3	19	63,654	N/A	+63,654
Add THA/TKA PRO-PM (Data Submission)	10	2	3,350	1	0.33	1,116.7	N/A	+1,116.7
Add Excessive Radiation eCQM	10	4	3,350	1	0.67	2,233.3	N/A	+2,233.3
Readopt with modification Hospital Outpatient Volume on Selected Outpatient Surgical Procedures	10	1	3,350	1	0.167	558.3	N/A	+558.3
	Total Change in Information Collection Burden Hours: +67,004							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+67,004) = **$1,492,875**							

BILLING CODE 4120–01–C

C. ICRs Related to the ASCQR Program

1. Background

We refer readers to the CY 2012 OPPS/ASC final rule (76 FR 74554), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53672), and the CY 2013 through CY 2023 OPPS/ASC final rules (77 FR 68532 through 68533; 78 FR 75172 through 75174; 79 FR 67015 through 67016; 80 FR 70582 through 70584; 81 FR 79863 through 79865; 82 FR 59479 through 59481; 83 FR 59156 through 59157; 84 FR 61469; 85 FR 86267; 86 FR 63968 through 63971; and 87 FR 72252 through 72253 respectively) for detailed discussions of the ASCQR Program ICRs we have previously finalized. The ICRs associated with the ASCQR Program for the CY 2014 through CY 2027 payment determinations are currently approved under OMB control number 0938–1270, which expires on August 31, 2025.

While the most recent data from the BLS reflects a median hourly wage of $24.56 per hour for medical records specialists generally, $26.06 is the hourly mean wage for medical records specialists in ''general medical and surgical hospitals,''[669] which we believe is more specific to our settings for use in our calculations than a position that may be found in other settings, such as ''office of physicians'' or ''nursing care facilities.'' We have finalized a policy to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage (81 FR 79863 through 79864). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method and allows for a conservative estimate of hourly costs.

Based on an analysis of the CY 2023 payment determination data, we found that, of the 5,697 ambulatory surgical centers (ASCs) that met eligibility requirements for the ASCQR Program, 5,181 ASCs received the full annual payment update (APU) because they complied with all applicable data reporting requirements for the ASCQR Program. In addition, 687 ASCs that were not required to participate in reporting did so, as well as 195 Hospitals Without Walls returned to active ASC billing, for a total of 6,063 participating facilities participating in the ASCQR Program. As noted in section XV.C.1 ''Regulatory Impact Analysis'' of this proposed rule, for the CY 2023 payment determination, all 5,181 ASCs that met eligibility requirements for the ASCQR Program received the APU including all facilities who were required, but exempted; 4,175 of these ASCs were required to participate without the public health emergency (PHE) exception (not applicable for current APU). On this basis, we estimate that 5,057 ASCs (4,175 + 687 + 195) will submit data for the ASCQR Program for the CY 2026 payment determination unless otherwise noted.

In section XV.B.4 of this proposed rule, we propose to modify three previously adopted measures: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure survey instrument usage, beginning with the voluntary CY 2024 reporting period; and (3) Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination. We also propose to re-adopt with modification the ASC Facility Volume on Selected ASC Surgical Procedures measure, beginning with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. Lastly, we propose to adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting, beginning with the voluntary CYs 2025 and 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

2. Information Collection Burden for the Proposal To Modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2022 OPPS/ASC proposed rule, we finalized adoption of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure for the ASCQR Program (86 FR 63875 through 63883). In section XV.B.4.a of this proposed rule, we propose to modify the COVID–19 Vaccination Coverage Among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and 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 the CY 2024 reporting period/CY 2026 payment determination for the ASCQR Program. We previously discussed information collection burden associated with this measure in the CY 2022 OPPS/ASC final rule (86 FR 63969).

We do not believe that the use of the term ''up to date'' or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted to CMS nor the frequency of data submission. Additionally, because we are not proposing any updates to the form, manner, and timing of data submission for this measure, we do not anticipate any increase in burden associated with this proposal. Furthermore, the modified COVID–19 Vaccination Coverage Among HCP measure would continue to be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date January 31, 2024). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (enacted on November 14, 1986) (NCVIA).[670]

3. Information Collection Burden for the Proposal To Modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery Measure Survey Instrument Use Beginning With the CY 2024 Reporting Period

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75126 through 75127), we finalized the adoption of the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the CY 2016 payment determination. In section XV.B.4.b of this proposed rule, we propose to limit the survey instruments that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R, beginning with the CY 2024 reporting period.

Because the three assessment tools being proposed are currently allowable for administering this measure, we do not believe limiting use to these three surveys would result in a change in burden. As a result, we are not proposing any changes in burden per response associated with this proposal. Additionally, as currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900.[671] We are not proposing an increase in the required sample size for chart abstraction; therefore we do not believe there is any increase in burden associated with this proposal.

[669] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

[670] Public Law 99–660.

[671] *https://qualitynet.cms.gov/files/62900933404aa300169072f1?filename=12.0_ASC_Full_Specs_Mnl.pdf.*

4. Information Collection Burden for the Proposal To Modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients Measure, Beginning With the CY 2024 Reporting Period/CY 2026 Payment Determination

In the CY 2014 OPPS/ASC final rule, we finalized the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure (78 FR 75127 through 75128). In section XV.B.4.c of this proposed rule, we propose to amend the measure denominator language by removing the removing the phrase ''aged 50 years'' and adding in its place the phrase ''aged 45 years.''

As currently stated in the ASCQR Program Specifications Manual, the maximum annual sample case size for chart abstraction for this measure is 63 cases for ASCs with an outpatient population size of between 0 and 900 and 96 cases for ASCs with an outpatient population size of greater than 900. We are not proposing an increase in the required sample size for chart abstraction; therefore, we do not believe there is any increase in burden associated with this proposal.

5. Information Collection Burden for the Proposal To Readopt With Modification the ASC Facility Volume on Selected ASC Surgical Procedures Measure With the Voluntary CY 2025 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2026 Reporting Period/CY 2028 Payment Determination

In section XV.B.5.a of this proposed rule, we propose to re-adopt with modification the ASC Facility Volume on Selected ASC SurgicalProcedures measure with the voluntary CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination. This measure was previously finalized in the CY 2012 OPPS/ASC final rule with a burden estimate of 10 minutes per response (76 FR 74554). This measure was subsequently removed from the ASCQR Program in the CY 2017 OPPS/ASC final rule with the same estimate of 10 minutes per response (82 FR 59479). Because this measure was originally adopted with the same burden estimate as the similar measure for the Hospital OQR Program, we continue to believe the burden per response is the same as the measure for the Hospital OQR Program, which we estimate to be 10 minutes per year in section XXIII.B.7 of this proposed rule. As a result, we estimate that each participating ASC would spend 10 minutes per year to collect and submit the data for this measure. For the voluntary CY 2025 reporting period, we assume 20 percent of ASCs will report data, resulting in an annual burden of 168.5 hours (5,057 ASCs × 20 percent × 0.167 hours) at a cost of $8,782 (168.5 hours × $52.12). For mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination, we estimate an annual burden of 843 hours (5,057 ASCs × 0.167 hours) at a cost of $43,937 (843 hours × $52.12).

6. Information Collection Burden for the Proposal To Adopt the Risk Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting, Beginning With the Voluntary CY 2025 and CY 2026 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2030 Payment Determination

In section XV.B.5.b of this proposed rule, we propose to adopt the THA/TKA PRO–PM, beginning with the voluntary CY 2025 and CY 2026 reporting periods, followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 7.25 minutes (0.120833 hours) per patient to complete both the pre-operative and post-operative surveys and 10 minutes (0.167 hours) per hospital per response to collect and submit the measure data via the HQR system (87 FR 49386 through 49387). We believe the estimated burden for both patient surveys and data submission would be the same for the ASCQR Program.

The THA/TKA PRO–PM uses four sources of data for the calculation of the measure: (1) patient-reported outcome (PRO) data; (2) claims data; (3) Medicare enrollment and beneficiary data; and (4) U.S. Census Bureau survey data. We estimate no additional burden associated with claims data, Medicare enrollment and beneficiary data, and U.S. Census Bureau survey data as these data are already collected via other mechanisms such as Medicare enrollment forms, CMS Form 1500, and U.S. Census Informational Questionnaires. While we are not proposing to require how ASCs collect PRO data for this measure, ASCs collecting PRO data would have multiple options for when and how they would collect these PRO data so they could best determine the mode and timing of collection that works best for their patient population.

The possible patient touchpoints for pre-operative PRO data collection include the doctor's office, pre-surgical steps such as education classes, or medical evaluations that could occur in an office or at the ASC. The modes of PRO data collection could include completion of the pre-operative surveys using electronic devices (such as an iPad or tablet), pen and paper, mail, telephone, or through a patient portal. Post-operative PRO data collection modes are similar to pre-operative modes. The possible patient touchpoints for post-operative data collection could occur before the follow-up appointment, at the doctor's office, or after the follow-up appointment. The potential modes of PRO data collection for post-operative data are the same as for pre-operative data. If the patient does not or cannot attend a follow-up appointment, the modes of collection could include completion of the post-operative survey using email, mail, telephone, or through a patient portal.

Similar to other surveys like the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey, we believe the use of multiple modes would maximize response rates as it allows for different patient preferences. For the THA/TKA PRO–PM data, ASCs would be able to submit data during two voluntary periods. The first voluntary reporting period would begin in CY 2025 for eligible procedures occurring between January 1, 2025 through December 31, 2025, and the second voluntary reporting period would begin with CY 2026 for eligible procedures occurring between January 1, 2026 through December 31, 2026. Voluntary reporting would be followed by mandatory reporting for eligible elective procedures beginning with the CY 2027 reporting period (occurring between January 1, 2027 through December 31, 2027), impacting the CY 2030 payment determination.

Whether participating in the voluntary reporting period or during subsequent mandatory reporting, ASCs would need to submit data twice (pre-operative data and post-operative data). For the purposes of calculating burden, we applied similar assumptions used for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49386 through 49387). Specifically, we estimate that, during the voluntary periods, 50 percent of ASCs that perform at least one THA/TKA procedure would submit data and

would do so for 50 percent of THA/TKA patients. For purposes of calculating burden for the mandatory period, we estimate that ASCs would submit for 100 percent of patients. While we propose to require ASCs to submit, at minimum, 50 percent of eligible, complete pre-operative data with matching eligible, complete post-operative data, we are conservative in our estimate for the mandatory period in case ASCs exceed this threshold.

To estimate the cost burden for patients completing the surveys for this proposed measure, we believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hour. We base this estimate on the Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, which identifies the approach for valuing time when individuals undertake activities on their own time.[672] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hour. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hour. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

To estimate the burden of information collection for patients completing surveys for this proposed measure, we assume that most ASCs would likely undertake PRO data collection through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. We estimate that approximately 42,706 THA/TKA procedures occur in an ASC each year, and that many patients could complete both the pre-operative and post-operative questionnaires. However, from our experience with using this measure in the Comprehensive Joint Replacement model, we are also aware that not all patients who complete the pre-operative questionnaire would complete the post-operative questionnaire. For the voluntary CY 2025 and CY 2026 reporting periods, we assume 10,677 patients would complete the survey (42,706 patients × 0.50 × 0.50 of ASCs) for a total of 1,290 hours annually (10,677 respondents × 0.120833 hours) at a cost of $26,716 (1,290 hours × $20.71) across all ASCs. Beginning with mandatory reporting in the CY 2027 reporting period/CY 2030 payment determination, we estimate a total of 5,160 hours (42,706 patients × 0.120833 hours) at a cost of $106,864 (5,160 hours × $20.71) across all ASCs.

Regarding ASCs' burden related to submitting data for this proposed measure, which would be reported via the HQR System, we estimate a burden of 10 minutes per response. ASCs would submit data associated with pre-operative surveys by March 31 of the CY following the CY in which the eligible procedures took place and would submit data associated with post-operative surveys by March 31 of the CY following the CY in which pre-operative data was submitted. Therefore, for the first voluntary reporting period for eligible procedures occurring in CY 2025, pre-operative survey data submission would occur in the first quarter of the CY 2026 reporting period and post-operative survey data submission would occur in the first quarter of the CY 2027 reporting period. For each of the two voluntary reporting periods, we estimate that each ASC would spend 20 minutes (0.33 hours) annually (10 minutes × 2 surveys) to collect and submit the data. For the voluntary CY 2026 reporting period, we estimate a burden for all participating ASCs of 422 hours (0.167 hours × 2,529 ASCs) at a cost of $21,995 (422 hours × $52.12). For the voluntary CY 2027 reporting period, we estimate a burden for all participating ASCs of 843 hours (0.33 hours × 2,529 ASCs) at a cost of $43,937 (843 hours × $52.12). For the mandatory CY 2028 reporting period, we estimate a burden for all participating ASCs of 1,264 hours [(0.167 hours × 2,529 ASCs) + (0.167 hours × 5,057 ASCs)] at a cost of $65,880 (1,264 hours × $52.12). For the CY 2029 reporting period and subsequent years, we estimate a total of 1,686 hours (0.33 hours × 5,057 ASCs) at a cost of $87,874 (1,686 hours × $52.12).

With respect to any costs or burdens unrelated to data submission, we refer readers to section XXVI.C.4.b ''Regulatory Impact Analysis'' of this proposed rule.

7. Summary of Information Collection Burden Estimates for the ASCQR Program

In summary, under OMB control number 0938–1270 (expiration date August 31, 2025), we estimate that the proposals in this proposed rule would result in an increase of 7,689 hours at a cost of $238,675 for 5,057 ASCs across a 6-year period from the CY 2024 reporting period/CY 2026 payment determination through the CY 2029 reporting period/CY 2030 payment determination. The following Tables 91 through 95 summarize the total burden changes for each respective CY payment determination compared to our currently approved information collection burden estimates (the table for the CY 2030 payment determination reflects the cumulative burden changes). We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1270.[673]

BILLING CODE 4120–01–P

[672] *http://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

[673] CY 2023 Final Rule ASCQR Program ''Supporting Statement-A''. Available at: *https://www.reginfo.gov/public/do/PRAView Document?ref_nbr=201911-0938-015.*

TABLE 91: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	2,529	4.2	0.51	1,290	N/A	+1,290
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	1,011	1	0.167	169	N/A	+169
	Total Change in Information Collection Burden Hours: +1,459							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+1,459) = **$35,498**							

TABLE 92: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2028 Payment Determinations							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	2,529	4.2	0.51	1,290	N/A	+1,290
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	2,529	1	0.167	422	N/A	+422
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
	Total Change in Information Collection Burden Hours: +2,555							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+2,555) = **$92,648**							

TABLE 93: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2029 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	2,529	1	0.33	843	N/A	+843
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
	Total Change in Information Collection Burden Hours: +6,846							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+6,846) **= $194,738**							

TABLE 94: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160
Add THA/TKA PRO-PM Measure (Voluntary Data Submission)	10	1	2,529	1	0.167	422	N/A	+422
Add THA/TKA PRO-PM Measure (Mandatory Data Submission)	10	1	5,057	1	0.167	843	N/A	+843
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
	Total Change in Information Collection Burden Hours: +7,268							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+7,268) = **$216,681**							

TABLE 95: SUMMARY OF ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2030 Payment Determination							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of OPPS ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Add THA/TKA PRO-PM Measure (Survey Completion)	3.625	2	5,057	8.4	1.02	5,160	N/A	+5,160
Add THA/TKA PRO-PM Measure (Data Submission)	10	2	5,057	1	0.33	1,686	N/A	+1,686
Readopt with modification ASC Facility Volume on Selected ASC Surgical Procedures	10	1	5,057	1	0.167	843	N/A	+843
	Total Change in Information Collection Burden Hours: +7,689							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+7,689) **= $238,675**							

BILLING CODE 4120–01–C

D. ICRs Related to the REHQR Program

1. Background

In section XVI. of this proposed rule, we discuss the requirements for the REH Quality Reporting (REHQR) Program. In this proposed rule, we propose to adopt four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT) Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility 7-Day Risk-Standardized Hospital Visit Rate after Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. As we are establishing the REHQR Program in this proposed rule, the ICRs associated with the REHQR Program will be submitted for OMB approval under a new OMB control number.

While the most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $24.56 per hour for all medical records specialists, $26.06 is the hourly mean wage for medical records specialists in ''general medical and surgical hospitals.'' [674] We believe specialists in ''general medical and surgical hospitals'' is more specific to our settings for use in our calculations than a position that may be found in other medical record specialist settings, such as ''office of physicians'' or ''nursing care facilities.'' We propose to calculate the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage similar to the policy previously finalized in the CY 2018 OPPS/ASC final rule for the Hospital OQR Program (82 FR 52617). This is necessarily a rough adjustment, both because fringe benefits and overhead costs can vary significantly from employer-to-employer and because methods of estimating these costs vary widely from study-to-study. Nonetheless, we believe that doubling the hourly wage rate ($26.06 × 2 = $52.12) to estimate the total cost is a reasonably accurate estimation method

[674] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on March 6, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

and allows for a conservative estimate of hourly costs.

Based on our analysis of CAHs and subsection (d) hospitals currently participating in the Hospital OQR Program with 50 beds or less, we have estimated 746 hospitals which would be both eligible to transition to REH status and are located in a State where legislation has passed as of March 2023 enabling transition to occur. We will revise this estimate in future rules when updated data are available.

2. Information Collection Burden for the Proposal To Adopt Three Claims-Based Measures Beginning With the CY 2024 Reporting Period

In sections XVI.B.5.a, XVI.B.5.c, and XVI.B.5.d of this proposed rule, we propose to adopt the following claims-based measures beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT) Use of Contrast Material measure; (2) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (3) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure. Because these measures are calculated using data that are already reported to the Medicare program for payment purposes, adopting these measures does not result in additional burden for REHs participating in the REHQR Program.

3. Information Collection Burden for the Proposal To Adopt the Median Time From ED Arrival to ED Departure for Discharged ED Patients Measure Beginning With the CY 2024 Reporting Period

In section XVI.B.5.b of this proposed rule, we propose to adopt the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2024 reporting period. This chart-abstracted measure was previously adopted as part of the Hospital OQR Program in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72086). Similar to reporting of this measure to the Hospital OQR Program as currently approved under OMB control number 0938–1109 (expiration date February 28, 2025), we estimate that chart-abstracted measures where patient-level data are submitted directly to CMS would take 2.9 minutes, or 0.049 hours. Further, based on sample size requirements for the measure in the Hospital OQR Program, we assume that each REH would similarly abstract and submit data from 63 cases per quarter, for a total of 252 cases per year.[675] We therefore estimate that it would take approximately 12.2 hours (0.049 hours × 252 cases) at a cost of approximately $636 per hospital (12.2 hours × $52.12/hour) to collect and report data for this measure. Therefore, for all participating REHs, we estimate an annual chart-abstraction burden of 9,101 hours (12.2 hours per REH × 746 REHs) at a cost of $474,344 per measure (9,101 hours × $52.12/hour).

4. Summary of Information Collection Burden Estimates for the REHQR Program

In summary, we estimate that the proposals in this proposed rule would result in an initial burden of 9,101 hours at a cost of $474,344 for 746 REHs annually beginning with the CY 2024 reporting period, as reflected in Table 96. We will submit these information collection estimates to OMB for approval as part of a new information collection request.

With respect to any costs/burdens unrelated to data submission, we refer readers to section XXVI.C.5.a ''Regulatory Impact Analysis'' of this proposed rule.

TABLE 96: SUMMARY OF REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements for the CY 2024 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Adopt Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure	2.9	1	746	252	12.2	9,101	0	+9,101
	Total Change in Information Collection Burden Hours: +9,101							
	Total Cost Estimate: Updated Hourly Wage ($52.12) x Change in Burden Hours (9,101) = **$474,344**							

[675] *https://qualitynet.cms.gov/files/63c8361058e56000179b310e?filename=OQR_v16.0a_SpecsManual_011723.pdf.*

E. ICRs Related to Conditions of Participation (CoPs): Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

To implement Division FF, section 4124 of the CAA 2023, we propose to modify the regulation text at § 485.914(a)(2) to include a cross-reference to § 485.918(g), which are additional requirements CMHCs must meet when assessing and admitting clients into the IOP program. At present, § 485.914(a)(2) solely pertains to PHP services with reference to § 485.918(f), which provides distinct criteria for clients evaluated and accepted for PHP services. We believe the burdens associated with these requirements are usual and customary business practice under 5 CFR 1320.3(b)(2). As such, the burden associated with these requirements is exempt from PRA; therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(a)(2).

We also propose to revise § 485.914(d)(2), which sets forth standards for updating a PHP client's comprehensive assessment no less frequently than every 30 days. We propose to add ''and IOP services,'' which would require the PHP and IOP client's interdisciplinary treatment team to update the assessment no less frequently than every 30 days. We believe that the burden associated with these requirements is the time required to update the comprehensive assessment and that this documentation is usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.914(d)(2).

F. ICRs Related to Conditions of Participation (CoPs): Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

We propose to modify § 485.916(d), which sets forth requirements for reviewing the person-centered active treatment plan. Currently, the interdisciplinary team is required to review, revise, and document the active treatment plan as frequently as the client's condition requires, but no less frequently than every 30 calendar days. A revised active treatment plan must include information from the client's updated comprehensive assessment and must document the client's progress toward the outcomes specified in the active treatment plan. CMHCs must also meet PHP program requirements specified under § 424.24(e) if such services are included in the active treatment plan. As Division FF, section 4124 of the CAA 2023 included coverage of IOP services for CMHCs, we believe it is necessary to add IOP services to this requirement and reference the specific IOP program requirements being proposed in section VIII.C.2 at § 424.24(d) of this proposed rule. We propose to cross-reference additional requirements specified under § 424.24(d) if a client's active treatment plan includes IOP services. The 2013 CMHC CoP final rule (78 FR 64603) included a burden for § 485.916(d) and is collected under OMB control number 0938–1245. The proposed revision to this requirement does not affect the burden. Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.916(d).

G. ICRs Related to Conditions of Participation (CoPs): Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

To implement Division FF, section 4124 of the CAA, 2023, which extended coverage of IOP services for CMHCs, we propose to revise the title of § 485.918 to include IOP services. The overall goal of this section is to ensure that the management structure is organized and accountable for the services furnished. We propose to add ''and intensive outpatient services'' to the end of the section heading.

The requirement at § 485.918(b) ''Standard: Provision of services'' specifies a comprehensive list of services that a CMHC must furnish. This list of services that CMHCs provide corresponds directly to the Statutory requirements in section 1861(ff)(3) of the Act. We propose to add ''and intensive outpatient services'' to § 485.918(b)(1)(iii), which states where specific services cannot be furnished, such as other than in an individual's home or an inpatient or residential setting, or psychosocial rehabilitation services. We believe that adding IOP services to § 485.918(b)(1)(iii) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we are not proposing to seek PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(b)(1)(iii).

We propose to add a new standard at § 485.918(g), ''Standard: Intensive Outpatient Services'', which will require all IOP services to meet all applicable requirements of 42 CFR 410 and 424. We also believe adding the IOP services requirement in the new proposed § 485.918(g) is a usual and customary business practice under 5 CFR 1320.3(b)(2). Therefore, we do not propose seeking PRA approval for any information collection or recordkeeping activities that may be conducted in connection with the proposed revisions to § 485.918(g).

H. ICRs Related to Hospital Price Transparency

In a final rule dated November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. We codified these requirements at new 45 CFR part 180.50 and 180.60, respectively.

The existing information collection requirement and the associated burden were finalized in the CY 2020 HPT final rule and are currently approved under OMB control number is 0938–1369, which expires on December 31, 2023. We originally estimated the number of hospitals to be 6,002. We finalized an initial one-time burden 150 hours and cost of $11,898.60 per hospital, resulting in a total national burden of 900,300 hours (150 hours × 6,002 hospitals) and $71,415,397 ($11,898.60 × 6,002 hospitals) to build processes and make required system updates to make their standard charge data publicly available: (1) as a comprehensive machine-readable file and (2) in a consumer-friendly format. Additionally, we estimated an on-going annual burden of 46 hours per hospital with a cost of $3,610.88 per hospital, resulting in a total national burden of 276,092 hours (46 hours × 6,002 hospitals) and total cost of $21,672,502 ($3,610.88 × 6,002 hospitals), to make required annual updates to the hospital's standard charge data information. For a detailed discussion of the cost estimates for the requirements related to hospitals making their standard charge data publicly available we refer readers to our discussion in the collection of information section in the CY 2020 HPT final rule (84 FR 65591 through 65596).

In section XVIII of this proposed rule, we propose to revise regulations at 45 CFR 180.50 related to making public hospital standard charges in an MRF.

First, we propose to add data elements to be included in the hospital's MRF and to require hospitals to conform to a CMS template layout. Second, to enhance automated access to the MRF, we propose that hospitals include a .txt file in the root folder of the public website it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields, and a link in the footer on its website that is labeled ''Hospital Price Transparency'' and links directly to the publicly available web page that hosts the link to the MRF. We believe these proposed revisions would result in an increased collection burden to hospitals, both in one-time cost and ongoing annual cost.

Additionally, we are increasing the number of hospitals we believe to be subject to these requirements from 6,002 to 7,098 which would increase the estimated national burden. In the CY 2020 HPT final rule (84 FR 65591), we estimated that 6,002 hospitals would be subject to the hospital price transparency requirements. To derive the estimated number, we relied on data from the American Hospital Association (AHA).[676] For this collection of information estimate, we are using updated hospital numbers based on the publicly available dataset from the Homeland Infrastructure Foundation-Level Data (HIFLD)[677] hospital dataset because the HIFLD dataset compiles a directory of hospital facilities based on data acquired directly from state hospital licensure information and federal sources, and validates this data annually. Thus, we believe the HIFLD dataset is more accurate than the AHA Directory. The source data was available in a variety of formats (pdfs, tables, web pages, etc.) which is reviewed and geocoded and then converted into a spatial database. To estimate the number of hospitals subject to these requirements, we leveraged the HIFLD hospital dataset to identify 8,013 total hospitals. We then subtracted out 379 hospitals HIFLD identified as ''closed'' as well as hospitals that are deemed under the regulation to have met requirements (see 45 CFR 180.30) which included 339 federally owned non-military and military hospitals, and 197 State, local, and district run forensic hospitals. We therefore estimate that this proposed rule applies to 7,098 hospitals operating within the United States under the definition of ''hospital.'' Finally, we estimate the hourly cost for each labor category used in this analysis by referencing Bureau of Labor Statistics report on Occupational Employment and Wages (May 2022)[678] in Table 97 below.

TABLE 97: OCCUPATION TITLES AND WAGE RATES

Occupational Title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
General and Operations Managers	BLS 11-1021	$59.07	$59.07	$118.14
Business Operations Specialists	BLS 13-1000	$40.04	$40.04	$80.08
Network and Computer Systems Administrators	BLS 15-1244	$46.71	$46.71	$93.42

First, we believe that hospitals would incur a one-time cost to update their processes and systems to (1) identify and collect the standard charge information represented by the newly proposed data elements, and (2) to conform the standard charge information for both the existing and newly proposed data elements in the proposed CMS template layout. To implement these requirements, we estimate that it would take, on average, 1 hour (at a cost of $118.14 per hour) for a General and Operations Manager (BLS 11–1021) to review and determine proposed compliance requirements. We estimate it will take a Business Operations Specialist (BLS 13–1000), on average, 10 hours (at a cost of $80.08 per hour) to develop and update the necessary processes and procedures and develop the requirements to implement the proposed CMS template. Once the existing systems have been identified and requirements developed, we estimate that a network and computer system administrator (BLS 15–1244) would spend, on average, 20 hours (at a cost of $93.42 per hour), to make updates to existing systems to conform to the proposed CMS template layout and post it to the internet, including developing and posting the proposed txt file in the root folder of the public web page it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields specified by this proposed rule. Therefore, we are finalizing the total annual burden estimate for the first year to be 31 hours (1 hours + 10 hours + 20 hours) per hospital with a cost of $2,787.34 ($118.14 + $800.80 + $1,868.40) per hospital. The one-time national burden is calculated to be $19,784,539.32 dollars ($2,787.34 per hospital × 7,098 hospitals). (See Table 98 below.)

[676] American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at: *https://www.aha.org/statistics/fast-facts-us-hospitals.* The AHA listed 6,210 total hospitals operating in the U.S. To arrive at 6,002 hospitals, we subtracted the 208 federally owned or operated hospitals.

[677] Homeland Infrastructure Foundation-Level Data hospital dataset accessed on May 3, 2023, located at *https://hifld-geoplatform.opendata.arcgis.com/datasets/hospitals/data.*

[678] U.S. Bureau of Labor Statistics, May 2022 national Occupational Employment and Wage Estimates United States, Occupational Employment and Wage Statistics. Accessed at *https://www.bls.gov/oes/tables.htm.*

TABLE 98: SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR THE FIRST YEAR

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180.50	0938-1369	7,098	7,098	31	220,038	$19,784,539.32

In addition to the one-time cost to implement the proposed CMS template, we are providing a revised estimate of our annual burden estimates. As noted, we originally estimated an on-going annual burden of 46 hours, per hospital, for 6,002 hospitals to make annual updates to display their standard charge data. Originally, we estimated it would take on average: a general or operations manager 2 hours, per hospital, to review and determine updates in compliance with requirements; a business operations specialist 32 hours, per hospital, to gather and compile required information and post it to the internet; and a network and computer system administrator 12 hours to maintain requirements specified in the CY 2020 HPT final rule (84 FR 65596).

We estimate it will still take a general or operations manager 2 hours, per hospital, to review and determine updates in compliance with requirements. However, we now estimate an increased ongoing amount of time for a business operations specialist, from 32 hours to 40 hours per hospital, to identify and gather required additional data elements on an annual basis. This increase acknowledges that some hospitals may not update their systems in the first year to maintain and abstract newly required data elements in an automated way to facilitate future annual updates to the MRF, thus we expect a subset of hospitals will continue to spend time annually to gather their standard charge information. We continue to believe that it will still take a computer system administrator 12 hours to maintain and post the MRF in a manner that conforms to the CMS template layout. Therefore, we estimate an annual national burden of 383,292 hours (54 hours × 7,098 hospitals) and an annual national cost of $32,370,571 dollars ($4,560.52 per respondent × 7,098 hospitals). This represents a $10,698,069 ($32,370,571 − $21,672,502) increase over our previous estimated national annual burden for subsequent years. We summarize our updated annual burden estimates in the Table 99 below.

TABLE 99: SUMMARY OF INFORMATION OF COLLECTION BURDENS FOR SUBSEQUENT YEARS

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180	0938-1369	7,098	7,098	54	383,292	$32,370,571

The new information collection requirements, as well as the one-time cost estimates and updated annual burden estimates discussed in this section will be submitted for OMB review and approval for OMB control number is 0938–1369.

If you comment on these information collection, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received on/by September 11, 2023.

XXV. 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.

XXVI. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2024. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2022, through and including December 31, 2022, and processed through June 30, 2023, and updated HCRIS cost report information, as discussed in section X.F of this proposed rule.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2024, enabling CMS to make changes to payment policies and payment rates for covered surgical

procedures and covered ancillary services that are performed in ASCs in CY 2024. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI–U for CY 2019 through 2023. In this CY 2024 OPPS/ASC proposed rule, we propose to extend the 5-year interim period to an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting. Further discussion of this proposed policy can be found in section XIII.G.2.b of this proposed rule.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this proposed rule, as required by Executive Order 12866, as amended, on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995, Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999)

Executive Orders 12866, as amended, and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled ''Modernizing Regulatory Review'' (hereinafter, the Modernizing E.O.) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely effect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) ($200 million or more in any 1 year). Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)) as measured by the $200 million or more in any 1 year. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2024, compared to CY 2023, due to the changes to the OPPS in this proposed rule, would be approximately $1.92 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2024, we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2024 will be approximately $88.6 billion, which is approximately $6.0 billion higher than estimated OPPS expenditures in CY 2023. Table 100 of this proposed rule displays the distributional impact of the CY 2024 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2024 policy, drugs and biologicals are generally proposed to be paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable. The impacts on hospital rates as a result of this proposed policy are reflected in the discussion of the estimated effects of this proposed rule.

We estimate that the proposed update to the conversion factor and other budget neutrality adjustments would increase total OPPS payments by 2.8 percent in CY 2024. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2023 and CY 2024, considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act would increase total estimated OPPS payments by 2.9 percent.

We estimate the total increase (from changes to the ASC provisions in this proposed rule, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2024 compared to CY 2023, to be approximately $220 million. Tables 101 and 102 of this proposed rule display the redistributive impact of the CY 2024 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in This Proposed Rule

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2024 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2024 on the CMS website with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.* On the website, select ''Regulations and Notices'' from the left side of the page and then select ''CMS–1786–P'' from the list of regulations and notices. The hospital-specific file layout and the hospital-specific file are listed with the

other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 100 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of OPPS Changes on Hospitals

Table 100 shows the estimated impact of this proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 100, and we discuss them separately below, because CMHCs have historically been paid only for partial hospitalization services under the OPPS and are a different provider type from hospitals. In CY 2024, we propose to pay CMHCs for partial hospitalization services under APCs 5853 (Partial Hospitalization (three services per day) for CMHCs) and 5854 (Partial Hospitalization (four or more services per day) for CMHCs) and to pay hospitals for partial hospitalization services under APCs 5863 (Partial Hospitalization (three services per day) for hospital-based PHPs) and 5864 (Partial Hospitalization (four or more services per day) for hospital-based PHPs). In addition, we propose to establish payment for four Intensive Outpatient Program (IOP) APCs, two for each provider type, including an APC for three services per day and an APC for four or more services per day.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2024 is 3.0 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.0 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is proposed to be 0.2 percentage point for CY 2024 (which is also the productivity adjustment for FY 2024 in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27005)), resulting in the proposed CY 2024 OPD fee schedule increase factor of 2.8 percent. We are using the OPD fee schedule increase factor of 2.8 percent in the calculation of the proposed CY 2024 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 100 of this proposed rule.

To illustrate the impact of the CY 2024 changes, our analysis begins with a baseline simulation model that uses the CY 2023 relative payment weights, the FY 2023 final IPPS wage indexes that include reclassifications, and the final CY 2023 conversion factor. Table 100 shows the estimated redistribution of the increase or decrease in payments for CY 2024 over CY 2023 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2023 and CY 2024 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.8 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the estimated impact taking into account all payments for CY 2024 relative to all payments for CY 2023, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 5).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2024. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2024 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2023 and CY 2024 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2024 would increase Medicare OPPS payments by an estimated 2.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 3.0 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 100 shows the total number of facilities (3,567), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2022 hospital outpatient and CMHC claims data to model CY 2023 and CY 2024 payments, by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2023 or CY 2024 payment and entities that are not paid under the OPPS. The latter entities include CAHs, all-inclusive hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed

in greater detail in section II.A of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,472), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their ''pre-BBA amount'' as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 27 CMHCs at the bottom of the impact table (Table 100) and discuss that impact separately below.

Column 2: APC Recalibration—All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals will experience a 0.0 increase, with the impact ranging from a decrease of 0.4 percent to an increase of 0.5, depending on the number of beds. Rural hospitals will experience an estimated increase of 0.4 overall. Major teaching hospitals will experience an estimated decrease of 0.3 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2024 IPPS post-reclassification wage indexes, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2023 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2024 changes in wage index policy, discussed in section II.C of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we are continuing the rural payment adjustment of 7.1 percent to rural SCHs for CY 2024, as described in section II.E of this proposed rule. We modeled a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2024 is 0.88, which is different from the 0.89 PCR target for the CY 2023 OPPS/ASC final rule with comment period (87 FR 71788). We note that, in accordance with section 16002 of the 21st Century Cures Act, we are applying a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.89, not the 0.88 target payment-to-cost ratio we propose to apply in section II.F of this proposed rule.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2024 scaled weights and a CY 2023 conversion factor that included a budget neutrality adjustment for the effect of the proposed changes to the wage indexes between CY 2023 and CY 2024.

Column 4: All Budget Neutrality Changes Combined With the Market Basket Update

Column 4 demonstrates the combined impact of all of the proposed changes previously described and the proposed update to the conversion factor of 2.8 percent. Overall, these changes would increase payments to urban hospitals by 2.8 percent and to rural hospitals by 4.7 percent. Rural sole community hospitals would receive an estimated increase of 4.9 percent while other rural hospitals would receive an estimated increase of 4.4 percent.

Column 5: All Changes for CY 2024

Column 5 depicts the full impact of the proposed CY 2024 policies on each hospital group by including the effect of all changes for CY 2024 and comparing them to all estimated payments in CY 2023. Column 5 shows the combined budget neutral effects of Columns 2 and 3; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of this proposed rule; the change in the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XIV of this proposed rule); and other proposed adjustments to the CY 2024 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2023 update (and assumed, for modeling purposes, to be the same number for CY 2023), we included 59 hospitals in our model because they had both CY 2022 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2024 would increase payments to all facilities by 2.9 percent for CY 2023. We modeled the independent effect of all changes in Column 5 using the final relative payment weights for CY 2023 and the proposed relative payment weights for CY 2024. We used the final conversion factor for CY 2023 of $85.585 and the proposed CY 2024 conversion factor of $84.788 discussed in section II.B of this proposed rule.

Column 5 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2024 IPPS/LTCH PPS proposed rule (87 FR 49427) of 5.8 percent (1.05755) to increase charges on the CY 2022 claims, and we used the overall CCR in the April 2023 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2023. Using the CY 2022 claims and a 5.8 percent charge inflation factor, we currently estimate that outlier payments for CY 2023, using a multiple threshold of 1.75 and a fixed-dollar threshold of $8,625, would be approximately 0.78 percent of total payments. The estimated current outlier payments of 0.78 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 11.8 percent (1.118412) and the CCRs in the April 2023 OPSF, with an adjustment of 0.977799 (88 FR 27221), to reflect relative changes in cost and charge inflation between CY 2022 and CY 2024, to model the proposed CY 2024 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $6,875. The charge inflation and CCR inflation factors are discussed in detail in the FY 2024 IPPS/LTCH PPS final rule (88 FR 27219 through 27223).

Overall, we estimate that facilities would experience an increase of 2.9 percent under this proposed rule in CY 2024 relative to total spending in CY 2023. This projected increase (shown in Column 5) of Table 100 of this proposed

rule reflects the proposed 2.8 percent OPD fee schedule increase factor, added by the difference in estimated outlier payments between CY 2023 (0.78 percent) and CY 2024 (1.0 percent), minus 0.10 percent for the change in the pass-through payment estimate between CY 2023 and CY 2024. We estimate that the combined effect of all changes for CY 2024 would increase payments to urban hospitals by 2.8 percent. Overall, we estimate that rural hospitals would experience a 4.4 percent increase as a result of the combined effects of all the changes for CY 2024.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes would include an increase of 2.4 percent for major teaching hospitals and an increase of 3.5 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 3.0 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 3.0 percent, proprietary hospitals would experience an increase of 3.4 percent, and governmental hospitals would experience an increase of 5.8 percent.

c. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 100 demonstrates the isolated impact on CMHCs, which historically have only furnished partial hospitalization services under the OPPS. As discussed in section VIII.D of this proposed rule, we propose for CY 2024 to pay CMHCs under APC 5853 (Partial Hospitalization (3 services per day) for CMHCs) for PHP days with three or fewer services, and APC 5854 (Partial Hospitalization (four or more services per day) for CMHCs) for days with four or more services. We modeled the impact of this APC policy assuming CMHCs will continue to provide the same PHP care as seen in the CY 2022 claims used for ratesetting in this proposed rule. We did not exclude days with one or two services from our modeling for CY 2024, because our proposed policy would pay the per diem rate for APC 5853 for such days beginning in CY 2024. As a result of the proposed PHP APC changes for CMHCs, we estimate that CMHCs would experience a 5.8 percent increase in CY 2024 payments relative to their CY 2023 payments (shown in Column 5). For a detailed discussion of our proposed PHP policies, please see section VIII of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2024 wage index values, which result in an estimated decrease of 1.0 percent to CMHCs. Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2024 and the proposed FY 2024 wage index updates, would result in an estimated increase of 5.9 percent.

Lastly, we note that as discussed in section VIII of this proposed rule, we propose to establish payment for intensive outpatient services furnished by CMHCs under APCs 5851 (Intensive Outpatient (3 services per day) for CMHCs) and 5852 (Intensive Outpatient (4 or more services per day) for CMHCs). Payment estimates for APCs 5851 and 5852 are not reflected in Table 100 but are discussed in section XXI.C.1.i of this proposed rule.

BILLING CODE 4120–01–P

TABLE 100: ESTIMATED IMPACT OF THE PROPOSED CY 2024 CHANGES FOR THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
ALL PROVIDERS *	3,567	0.0	0.1	2.9	2.9
ALL HOSPITALS	3,472	0.1	0.2	3.0	3.0
(excludes hospitals held harmless and CMHCs)					
URBAN HOSPITALS	2,761	0.0	0.0	2.8	2.8
LARGE URBAN	1,430	0.0	-0.1	2.7	2.8
(GT 1 MILL.)					
OTHER URBAN	1,331	0.0	0.2	3.0	2.8
(LE 1 MILL.)					
RURAL HOSPITALS	711	0.4	1.4	4.7	4.4
SOLE COMMUNITY	375	0.3	1.7	4.9	4.4
OTHER RURAL	336	0.6	0.9	4.4	4.3
BEDS (URBAN)					
0 - 99 BEDS	934	0.5	0.1	3.4	3.2
100-199 BEDS	778	0.5	-0.1	3.2	3.2
200-299 BEDS	421	0.2	0.1	3.1	3.0
300-499 BEDS	397	0.0	0.7	3.4	3.2
500 + BEDS	231	-0.4	-0.4	2.0	2.1
BEDS (RURAL)					
0 - 49 BEDS	342	0.8	1.2	4.9	4.6
50- 100 BEDS	213	0.5	2.1	5.5	5.1
101- 149 BEDS	81	0.4	1.2	4.4	3.7
150- 199 BEDS	42	0.2	1.4	4.5	4.0
200 + BEDS	33	0.0	0.8	3.6	3.7
REGION (URBAN)					
NEW ENGLAND	131	0.1	-2.4	0.5	0.6
MIDDLE ATLANTIC	306	-0.1	1.4	4.1	4.2
SOUTH ATLANTIC	458	0.0	-0.6	2.2	2.3
EAST NORTH CENT.	419	0.0	-0.8	2.0	2.1
EAST SOUTH CENT.	158	-0.3	-0.2	2.3	2.3
WEST NORTH CENT.	183	-0.2	0.3	2.9	1.7
WEST SOUTH CENT.	459	0.2	-0.5	2.5	2.6
MOUNTAIN	210	0.0	-1.7	1.1	0.9
PACIFIC	388	0.2	2.7	5.7	5.8

	(1)	(2)	(3)	(4)	(5)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
PUERTO RICO	49	0.2	-0.6	2.3	2.3
REGION (RURAL)					
NEW ENGLAND	19	0.2	-1.0	2.0	2.4
MIDDLE ATLANTIC	47	0.3	8.3	11.6	11.5
SOUTH ATLANTIC	106	0.5	0.5	3.9	3.8
EAST NORTH CENT.	112	0.4	0.7	3.9	3.9
EAST SOUTH CENT.	139	0.7	0.2	3.6	3.6
WEST NORTH CENT.	85	0.2	1.8	4.8	3.7
WEST SOUTH CENT.	133	1.0	0.3	4.2	4.1
MOUNTAIN	46	0.2	0.9	3.9	2.0
PACIFIC	24	0.2	3.9	7.0	7.0
TEACHING STATUS					
NON-TEACHING	2,186	0.4	0.4	3.6	3.5
MINOR	872	0.1	0.3	3.2	3.0
MAJOR	414	-0.3	-0.2	2.2	2.4
DSH PATIENT PERCENT					
0	7	-0.9	-0.7	1.1	3.4
GT 0 - 0.10	247	-0.1	-0.3	2.4	2.2
0.10 - 0.16	248	0.3	-0.1	3.0	3.0
0.16 - 0.23	568	0.3	0.0	3.1	3.0
0.23 - 0.35	1,135	0.0	0.1	2.9	2.7
GE 0.35	852	-0.2	0.6	3.3	3.4
DSH NOT AVAILABLE **	415	7.1	1.5	11.7	12.2
URBAN TEACHING/DSH					
TEACHING & DSH	1,142	-0.1	0.0	2.6	2.6
NO TEACHING/DSH	1,197	0.3	0.1	3.3	3.2
NO TEACHING/NO DSH	7	-0.9	-0.7	1.1	3.4
DSH NOT AVAILABLE2	415	7.1	1.5	11.7	12.2
TYPE OF OWNERSHIP					
VOLUNTARY	1,985	0.0	0.3	3.1	3.0
PROPRIETARY	1,047	0.7	-0.1	3.5	3.4
GOVERNMENT	440	-0.2	0.0	2.7	2.8
CMHCs	27	4.0	-1.0	5.9	5.8
Column (1) shows total hospitals and/or CMHCs.					
Column (2) includes all proposed CY 2024 OPPS policies and compares those to the CY 2023 OPPS.					

		(1)	(2)	(3)	(4)	(5)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**All Changes**
Column (3) shows the budget neutral impact of updating the wage index by applying the proposed FY 2024 hospital inpatient wage index. The proposed rural SCH adjustment would continue our current policy of 7.1 percent, so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0005 because the proposed CY 2024 target payment-to-cost ratio is less than the CY 2023 PCR target.						
Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.8 percent OPD fee schedule update factor (3.0 percent reduced by 0.2 percentage point for the productivity adjustment).						
Column (5) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.						
*These 3,567 providers include children's and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.						
** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.						

BILLING CODE 4120–01–C

d. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments will rise and will decrease for services for which the OPPS payments will fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18.0 percent for all services paid under the OPPS in CY 2024. The estimated aggregate beneficiary coinsurance reflects general system adjustments, including the proposed CY 2024 comprehensive APC payment policy discussed in section II.A.2.b of this proposed rule. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

e. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII of this proposed rule. Hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule. Additionally, as discussed in section VIII of this proposed rule, we propose to establish payment for IOP furnished by RHCs, FQHCs, and OTPs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 100; however, the proposed payment amount for OPPS APC 5861 would affect payments to these providers. We discuss estimated effects of proposed IOP policies in section XXI.C.1.i of this proposed rule.

f. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of $1.9 billion in program payments for OPPS services furnished in CY 2024. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this proposed rule would increase these Medicaid beneficiary payments by approximately $115 million in CY 2024. Currently, there are approximately 10 million dual-eligible beneficiaries, which represent approximately 30 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 30 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 57 percent Federal payments and 43 percent State payments. Therefore, for the estimated $115 million Medicaid increase, approximately $65 million would be from the Federal Government and $50 million will be from State governments.

g. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we propose and the reasons for our selected alternatives are discussed throughout this proposed rule.

- Alternatives Considered for the Claims Data used in OPPS and ASC Ratesetting due to the PHE.

We refer readers to section X.F. of this proposed rule for a discussion of our proposed policy of returning to the standard update process of using updated cost report data for OPPS ratesetting. In that section, we discuss our consideration of issues regarding data updates, and in particular the selection of cost report data used, which would include some cost report data including the timeframe of the PHE. We

note that were we to continue using cost report data from prior to the PHE it would potentially not be reflective of more updated cost and charging patterns. In this proposed rule, as discussed in section X.F. of this proposed rule, we propose a policy of resuming our regular cost report update process for CY 2024 OPPS ratesetting.

We note that these policy considerations also have ASC implications since the relative weights for certain surgical procedures performed in the ASC setting are developed based on the OPPS relative weights and claims data.

h. Health Equity Comment Solicitation

Advancing health equity is the first pillar of the CMS 2022 Strategic Framework.[679] To gain insight into how OPPS and ASC policies could affect health equity, we are considering adding elements to our impact analysis that would detail how OPPS and ASC policies impact particular beneficiary populations. Beneficiary populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes; people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency; members of rural communities; and persons otherwise adversely affected by persistent poverty or inequality.

We are seeking comment from interested parties about how we might structure an impact analysis that addresses how OPPS and ASC changes may impact beneficiaries of different groups. We currently present OPPS impacts by provider type, rural versus urban area, geographic region, teaching status, and ownership type. We are interested in what health equity questions we can examine within these existing categories to better understand the heath equity impact of our policies. We also welcome suggestions about adding new categories or measures of health equity in our impact analyses, such as using the area deprivation index (ADI) as a proxy for disparities related to geographic variation. Additionally, we are seeking comment on ways to continue building an OPPS health equity framework that allows us to develop policies that enhance health equity under our existing statutory authority.

[679] Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

i. Effects of Proposed IOP Policies on Hospitals, CMHCs, FQHCs, RHCs, and OTPs

As discussed in section VIII of this proposed rule, we propose to establish payment for intensive outpatient services furnished by hospitals, CMHCs, FQHCs, and RHCs under a new IOP benefit. We also propose to establish payment for intensive outpatient services provided by OTPs under the existing OTP benefit. Estimates of the payment impacts for IOP furnished by hospitals are included in Table 100 of this proposed rule, based on utilization in the CY 2022 claims for days that we believe would likely be billed as IOP beginning in CY 2024. Specifically, we modeled non-PHP days furnished by hospitals with 3 and 4 or more services from Table 43 of this proposed rule and at least one service from the list of primary services shown in Table 44 of this proposed rule.

Because CMHCs are currently only permitted to bill for partial hospitalization services, we are unable to model payments for IOP APCs 5851 and 5852 based on utilization from CY 2022 claims. Therefore, the payment impacts for IOP furnished by CMHCs are not included in Table 100. However, we anticipate there would be an increase in utilization for CMHCs beginning in CY 2024. We simulated potential utilization for IOP APCs 5851 and 5852 based on estimates of the volume of such services that we expect would be provided beginning in CY 2024. We calculated the number of non-PHP 3-service and 4-service days in the hospital setting, and compared this to the number of PHP 3-service and 4-service days in the hospital setting. We applied the same ratio of non-PHP to PHP days to estimate anticipated IOP claims in the CMHC setting for CY 2024. We believe this is appropriate, because as discussed in section VIII.C of this proposed rule, we propose that IOP and PHP days would consist of the same services and use the same HCPCS codes. Therefore, for public awareness, we are including projections about potential IOP utilization for CMHCs using claims with a comparable number and type of services, which we believe is the best available estimate of IOP utilization in the future. Based on this methodology, we estimate that CMHCs would provide approximately 35,511 IOP days with three services and approximately 22,558 IOP days with four or more services. These projections correspond to an estimated $6,593,452 in additional payments to CMHCs for the provision of intensive outpatient services. This represents an increase of roughly 165 percent relative to current CMHC payments for partial hospitalization services. We solicit comment on our assumptions and the methodology used to derive this estimate.

In section VIII.F.4 of this proposed rule, we discuss the special payment rules for FQHCs and RHCs to furnish intensive outpatient services as mandated by sections 4124(c)(1) and (c)(2) of the CAA, 2023. For both FQHCs and RHCs, we propose to set the IOP payment rate as based on the per diem payment amount determined for APC 5861 (Intensive Outpatient (3 services per day) for hospital-based IOPs). However, for IOP services furnished in FQHCs, we propose that that payment amount is based on the lesser of a FQHC's actual charges or the rate determined for APC 5861. Additionally, we propose that grandfathered tribal FQHCs will continue to have their payment based on the outpatient per visit rate when furnishing IOP services. That is, payment is based on the lesser of a grandfathered tribal FQHC's actual charges or the outpatient per visit rate.

FQHCs and RHCs currently bill for mental health services. Beginning January 1, 2024 these settings will be able to bill for certain mental health services determined to be IOP services that they were not able to furnish previously, for example group therapy. We anticipate there would be utilization of IOP services for both RHCs and FQHCs in CY 2024; however, since this is a new program for both settings, we are unable to project what that utilization would be or the associated Medicare expenditures. FQHCs and RHCs typically furnish primary care services therefore we believe that it may take time for these settings to build the internal framework needed to initiate and foster an IOP. With regard to RHCs, we note the statutory provision which defines the term ''rural health clinic'' in section 1861(aa)(2)(K)(iv) of the Act, states that a RHC is not a facility which is primarily for the care and treatment of mental diseases. We believe this provision could cause low utilization of IOP services until RHCs can determine what they can or cannot furnish. Therefore, we believe extending coverage for IOP services in FQHCs and RHCs is unlikely to have a significant impact on overall Medicare spending.

As discussed in section VIII.G of this proposed rule, for CY 2024 and subsequent years, we propose to establish a weekly add-on code for IOP services furnished by OTPs for the treatment of opioid use disorder (OUD) and to revise the definition of OUD treatment services to include IOP services. In accordance with our

methodology for other add-on adjustments to the bundled payment for OUD treatment services, we propose to apply an annual update based on the Medicare Economic Index (MEI) described in § 414.30, and apply a geographic adjustment based on the Geographic Adjustment Factor (GAF) described in § 414.26. Under this proposal, we would permit OTPs to bill a new HCPCS code (GOTP1) for IOP services based on a minimum of at least nine IOP services furnished to eligible patients per week, which would result in a payment rate of $719.67.

We estimate that these proposed policies to allow OTPs to bill for IOP services beginning in CY 2024 would result in a negligible cost increase. In our analysis, we evaluated mental health services furnished to beneficiaries receiving care at OTPs, including for levels of care and types of services that are not currently reflected in the OTP benefit. Approximately 557 OTPs offer IOP services nationwide according to the National Substance Use and Mental Health Services Survey in 2021.[680] However, our analysis of claims data from Medicare beneficiaries receiving care under the OTP benefit from CY 2020–2022 indicated a small number of beneficiaries actually receive intensive care services equivalent to 9 hours or more a week to meet the minimum threshold for IOP services. Specifically, 85 percent of Medicare beneficiaries received only medications for OUD with basic counseling and no other mental health care, and thus did not likely utilize a higher level of care required for IOP services. For the remaining 15 percent of Medicare beneficiaries, approximately 0.5–0.7 percent received a higher acuity of care likely to meet the minimum 9 hours or more of services under IOPs. The estimated total annual cost per Medicare beneficiary with an OUD receiving IOP services at an OTP would be approximately $38,000, however, this estimate assumes that a beneficiary would require this level of care every week of the calendar year, which we do not believe would be likely. Therefore, extending coverage for IOP services in OTP settings is unlikely to have a significant impact on overall Medicare spending.

[680] Substance Abuse and Mental Health Services Administration, National Substance Use and Mental Health Services Survey (N–SUMHSS), 2021: Annual Detailed Tables. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2023. Weblink: *https://www.samhsa.gov/data/sites/default/files/reports/rpt39450/2021%20N-SUMHSS%20Annual%20Detailed%20Tables_508_Compliant_2_8_2023.pdf.*

2. Estimated Effects of CY 2024 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII of this proposed rule, we are setting the CY 2024 ASC relative payment weights by scaling the proposed CY 2024 OPPS relative payment weights by the proposed CY 2024 ASC scalar of 0.8649. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 101 and 102.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period, ending with the applicable fiscal year, year, cost reporting period, or other annual period). For ASCs that fail to meet their quality reporting requirements, the CY 2024 payment determinations would be based on the application of a 2.0 percentage point reduction to the annual update factor, which would be the hospital market basket update for CY 2024. We calculated the proposed CY 2024 ASC conversion factor by adjusting the CY 2023 ASC conversion factor by 1.0017 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2023 and CY 2024 and by applying the CY 2024 productivity-adjusted hospital market basket update factor of 2.8 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.0 percent reduced by a productivity adjustment of 0.2 percentage point). The proposed CY 2024 ASC conversion factor is $53.397 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2024 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2022 and CY 2024 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2024 changes will be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as eye, digestive system, or orthopedic procedures. The combined effect of the proposed update to the CY 2024 payments on an individual ASC will depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2024 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2022 claims data. Table 101 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2023 payments to estimated CY 2024 payments, and Table 102 shows a comparison of estimated CY 2023 payments to estimated CY 2024 payments for procedures that we estimate would receive the most Medicare payment in CY 2023.

In Table 101, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 101.

• Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group, which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

• Column 2—Estimated CY 2023 ASC Payments were calculated using CY 2022 ASC utilization data (the most recent full year of ASC utilization) and CY 2023 ASC payment rates. The surgical specialty groups are displayed in descending order based on estimated CY 2023 ASC payments.

• Column 3—Estimated CY 2024 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2024 compared to CY 2023.

As shown in Table 101, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the final update to ASC payment rates for CY 2023 will result in a 6 percent increase in aggregate payment amounts for eye and ocular adnexa procedures, a 6 percent decrease in aggregate payment amounts for nervous system procedures, 3 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 7 percent increase in aggregate payment amounts for digestive system procedures, a 4 percent increase in aggregate payment amounts for cardiovascular system procedures, and a 6 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.8 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.8 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 6 percent increase in aggregate eye and ocular adnexa procedure payments. The increase in payment rates for eye and ocular andexa procedures is a result of increased OPPS relative weights as a result of the APC restructuring to the Intraocular APC family and is further increased by the 2.8 percent ASC rate update for these procedures. Conversely, we estimate a 6 percent decrease in nervous system procedures related to the American Medical Association's RVU Update Committee (RUC) estimated shift in utilization from an existing high-cost neurostimulator procedure (CPT code 64685) to a new, lower-cost neurostimulator procedure (CPT code 0X43T) for CY 2024. For estimated changes for selected procedures, we refer readers to Table 101 provided later in this section.

TABLE 101: ESTIMATED IMPACT OF THE PROPOSED CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2023 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2023 ASC Payments (in Millions) (2)	Estimated CY 2024 Percent Change (3)
Total	$6,309	3
Eye	$1,880	6
Nervous System	$1,274	-6
Musculoskeletal	$1,188	3
Gastrointestinal	$937	7
Cardiovascular	$276	4
Genitourinary	$225	6

Table 102 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2024. The table displays 30 of the procedures receiving the greatest estimated CY 2023 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2023 program payment.

• Column 1—CPT/HCPCS code.

• Column 2—Short Descriptor of the HCPCS code.

• Column 3—Estimated CY 2023 ASC Payments were calculated using CY 2022 ASC utilization (the most recent full year of ASC utilization) and the CY 2023 ASC payment rates. The estimated CY 2023 payments are expressed in millions of dollars.

• Column 4—Estimated CY 2024 Percent Change reflects the percent differences between the estimated ASC payment for CY 2023 and the estimated payment for CY 2024 based on the proposed update.

BILLING CODE 4120–01–P

TABLE 102: ESTIMATED IMPACT OF THE PROPOSED CY 2024 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2023 ASC Payment (in millions) (3)	Estimated CY 2024 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,251	6
63685	Insrt/redo spine n generator	$314	-37
27447	Total knee arthroplasty	$263	1
45380	Colonoscopy and biopsy	$244	6
45385	Colonoscopy w/lesion removal	$213	6
63650	Implant neuroelectrodes	$194	-10
43239	Egd biopsy single/multiple	$158	7
27130	Total hip arthroplasty	$130	1
66991	Xcapsl ctrc rmvl insj 1+	$113	15
64590	Insrt/redo pn/gastr stimul	$106	-15
64483	Njx aa&/strd tfrm epi l/s 1	$100	4
66982	Xcapsl ctrc rmvl cplx wo ecp	$94	6
J1097	Phenylep ketorolac opth soln	$82	-1
64635	Destroy lumb/sac facet jnt	$76	2
29827	Sho arthrs srg rt8tr cuf rpr	$75	6
36902	Intro cath dialysis circuit	$67	7
64493	Inj paravert f jnt l/s 1 lev	$66	4
G0105	Colorectal scrn; hi risk ind	$65	7
27279	Arthrodesis sacroiliac joint	$63	-2
66821	After cataract laser surgery	$61	7
64561	Implant neuroelectrodes	$53	4
65820	Relieve inner eye pressure	$45	3
C9740	Cysto impl 4 or more	$45	3
62323	Njx interlaminar lmbr/sac	$41	4
G0121	Colon ca scrn not hi rsk ind	$40	7
15823	Revision of upper eyelid	$38	4
45378	Diagnostic colonoscopy	$37	7
0275T	Perq lamot/lam lumbar	$36	5
64721	Carpal tunnel surgery	$36	2
J1096	Dexametha opth insert 0.1 mg	$34	-2

BILLING CODE 4120–01–C

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2024 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the new procedures to be designated as office-based for CY 2024. First, other than certain preventive services where coinsurance and the Part B deductible is waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will almost always be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For

those additional procedures that we proposed to designate as office-based in CY 2024, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A–4 (available on the Office of Management and Budget website at: *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/assets/OMB/circulars/a004/a-4.html*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule. The first accounting statement, Table 103, illustrates the classification of expenditures for the CY 2024 estimated hospital OPPS incurred benefit impacts associated with the final CY 2024 OPD fee schedule increase. The second accounting statement, Table 104, illustrates the classification of expenditures associated with the 2.8 percent CY 2024 update to the ASC payment system, based on the provisions of this proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers. Table 105 includes the annual estimated impact of hospital OQR and ASCQR programs.

BILLING CODE 4120–01–P

TABLE 103: ACCOUNTING STATEMENT: CY 2024 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2023 TO CY 2024 ASSOCIATED WITH THE CY 2024 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1,920 million
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 104: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2023 TO CY 2024 AS A RESULT OF THE PROPOSED CY 2024 UPDATED TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$130 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$130 million

TABLE 105: ESTIMATED COSTS IN CY 2024

CATEGORY	Costs
Burden	$-11,688,943 million*
Regulatory Familiarization	$17.204 million**

*The annual estimate includes the impact of Hospital OQR and ASCQR Programs.
** Regulatory familiarization costs occur upfront only.

BILLING CODE 4120–01–C

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2023 OPPS/ASC final rule (87 FR 72278 through 72279) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2025 payment determination. Of the 3,097 hospitals that met eligibility requirements for the CY 2023 payment determination for the Hospital OQR Program, we determined that 77 hospitals did not meet the requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor.

b. Impact of CY 2024 OPPS/ASC Proposed Rule Policies

We do not anticipate that the proposed Hospital OQR Program policies would significantly impact the number of hospitals that will receive payment reductions. In this proposed rule, we propose to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Appropriate

Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO–PM), beginning with the voluntary CYs 2025 and 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination; (5) adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) electronic clinical quality measure (eCQM), beginning with the CY 2025 voluntary reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; (6) re-adopt with modification the Hospital Outpatient Volume Data on Selected Outpatient Surgical Procedures measure, beginning with voluntary reporting for the CY 2025 reporting period and mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (7) remove the Left Without Being Seen measure beginning with the CY 2024 reporting period/CY 2026 payment determination.

We refer readers to section XXIV.B of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Hospital OQR Program where we state that for purposes of burden estimation, 3,350 hospitals will be considered and Table 89 where we estimate a total information collection burden increase for 3,350 OPPS hospitals of 67,004 hours at a cost of $1,492,875 annually associated with our proposed policies for the CYs 2024 reporting period/CY 2026 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XIV.B.2.a of this proposed rule, we propose to modify the COVID–19 Vaccination Coverage among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and 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. Although we anticipate this modification may require some hospitals to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most hospitals are currently recording all necessary information for HCP such that this modification would not require additional information to be collected. Therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule for the Hospital OQR Program (86 FR 63984).

In section XIV.B.2.b of this proposed rule, we propose to modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure by limiting the survey instrument that can be used to administer this measure to three assessment tools: National Eye Institute Visual Function Questionnaire (NEI VFQ–25), Visual Function Index (VF–14), and VF–8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some hospitals may be currently using one of the other surveys which would no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices would be negligible as these surveys are all publicly available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XIV.B.3.b of this proposed rule, we propose the adoption of the THA/TKA PRO–PM. We assume the effects on outpatient hospitals would be similar to the effects previously discussed in the FY 2023 IPPS/LTCH PPS final rule for the inpatient hospital setting under the Hospital Inpatient Quality Reporting (IQR) Program (87 FR 49492). For hospitals that would not already be collecting these data for the Hospital IQR Program, there would be some non-recurring costs associated with changes in workflow and IT systems to collect the data for the Hospital OQR Program. The extent of these costs is difficult to quantify as different hospitals may utilize different modes of data collection (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of hospitals would report data for this measure directly to CMS via the CMS-designated information system (currently, the Hospital Quality Reporting (HQR) system), we assume some hospitals may elect to submit measure data using a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) measure (OMB control number 0938–098; expiration date September 30, 2024), which used an estimate of approximately $4,000 per hospital to account for these costs. This per hospital cost estimate originates from this Paperwork Reduction Act analysis performed for 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $5,212 ($4,000 × 130.3 percent).[681]

In section XIV.B.3.c of this proposed rule, we propose the adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM. Similar to the CY 2022 OPPS/ASC final rule (86 FR 63837 through 63840), we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' electronic health record (EHR) systems for the eCQMs used in the Hospital OQR Program (83 FR 41771).

Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV ''Collection of Information'' of this proposed rule, if adopted.

4. Effects of Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

In section XV of this proposed rule, we discuss our proposed policies affecting the ASCQR Program. For the CY 2023 payment determination, of the 5,697 Ambulatory Surgical Centers (ASCs) that met eligibility requirements, we determined that 516 ASCs did not meet the requirements to receive the full annual payment rate update under the ASC fee schedule.

[681] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 9, 2023. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf.*

b. Impact of CY 2024 OPPS/ASC Proposed Policies

In this proposed rule, we propose to: (1) modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure beginning with the voluntary CY 2024 reporting period; (3) modify the Endoscopy/Polyp Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (4) re-adopt with modification the ASC Facility Volume Data on Selected ASC Surgical Procedures measure, beginning with voluntary reporting for the CY 2025 reporting period followed by mandatory reporting beginning with the CY 2026 reporting period/CY 2028 payment determination; and (5) adopt the Risk-Standardized Patient-Reported Outcome-Based Performance Measure (PRO–PM) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO–PM), beginning with voluntary CYs 2025 and CY 2026 reporting periods followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2030 payment determination.

We refer readers to section XXIV.C of this proposed rule (information collection requirements) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the ASCQR Program and Table 94 where we estimate a total information collection burden increase for 5,057 ACSs of 7,689 hours at a cost of $238,675 annually associated with our proposed policies and updated burden estimates for the CY 2025 reporting period/CY 2027 payment determination and subsequent years, compared to our currently approved information collection burden estimates.

In section XV.B.4.a of this proposed rule, we propose to modify the COVID–19 Vaccination Coverage among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and 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. Although we anticipate this modification may require some facilities to update information technology (IT) systems or workflow related to maintaining accurate vaccination records for HCP, we assume most facilities are currently recording all necessary information for HCP such that this modification would not require additional information to be collected and, therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the CY 2022 OPPS/ASC final rule for the ASCQR Program (86 FR 63985).

In section XV.B.4.b of this proposed rule, we propose to modify the Cataracts: Improvement in Patient's Visual Function Within 90 Days Following Cataract Surgery measure by limiting the survey instrument that can be used to administer this measure to three assessment tools: NEI VFQ–25, VF–14, and VF–8R. These surveys were found to have fewer noted limitations, present the lowest administrative burden, and achieve adequate validity and reliability compared to other surveys. We understand some ASCs may be currently using one of the other surveys which would no longer be allowable for collecting data for this measure, however, we believe any costs associated with modifying clinical practices would be negligible as these surveys are all publicly available at no additional cost and are comparable survey instruments in form and manner for data collection and measure calculation to other surveys used for this measure.

In section XV.B.5.b of this proposed rule, we propose the adoption of the THA/TKA PRO–PM. We assume the effects on ASCs would be similar to those previously finalized for the inpatient hospital setting under the Hospital IQR Program as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49492). For ASCs that are not currently collecting these data, there would be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different ASCs may utilize different modes of data collection (such as paper-based, electronically patient-directed, or clinician-facilitated). While we assume the majority of ASCs would report data for this measure directly to CMS via the CMS-designated information system (currently, the HQR System), we also assume some ASCs may elect to submit measure data via a third-party vendor, for which there are associated costs. To determine an estimate of third-party vendor costs, we looked at the HCAHPS measure (OMB control number 0938–0981; expiration date September 30, 2024), which used an estimate of approximately $4,000 per hospital to account for these costs. This estimate originates from 2012, therefore, to account for inflation (assuming end of CY 2012 to January CY 2023), we adjust the price using the Bureau of Labor Statistics Consumer Price Index and estimate an updated cost of approximately $5,212 ($4,000 × 130.3 percent).[682]

Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV ''Collection of Information'' of this proposed rule, if adopted.

5. Effects of Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

In section XVI of this proposed rule, we discuss our proposed policies affecting the REHQR Program. We propose to adopt four new measures, beginning with the CY 2024 reporting period: (1) the Abdomen Computed Tomography (CT)—Use of Contrast Material measure; (2) the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure; (3) the Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy measure; and (4) the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery measure.

We refer readers to section XXIV.D ''Collection of Information'' of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the REHQR Program and Table 96 where we estimate a total information collection burden for 746 REHs of 9,101 hours at a cost of $474,344 annually associated with our proposed policies for the CY 2024 reporting period and subsequent years. Regarding the remaining proposals, we do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XXIV ''Collection of Information'' of this proposed rule, if adopted.

b. Impact of CY 2024 OPPS/ASC Proposed REHQR Program Policies

For CY 2024, we have determined there are 1,716 CAHs and rural subsection (d) hospitals with 50 or fewer beds that are eligible to convert to

[682] U.S. Bureau of Labor Statistics. Historical CPI–U data. Accessed on March 9, 2023. Available at: *https://www.bls.gov/cpi/tables/supplemental-files/historical-cpi-u-202301.pdf.*

become an REH in the nation. Based on the March 2023 numbers of REH-eligible hospitals currently in the Hospital OQR program and in states with REH licensure provisions, we estimate 746 hospitals which could convert to REH status, and we use this number of REHs for our impact analyses. We acknowledge that the number of conversions could be less than or significantly greater than this estimate.

As hospitals eligible to convert to REH status have been eligible to report quality measures under the Hospital OQR Program and most of these hospitals have been reporting, we do not believe any of our administrative proposals would result in additional impact on these hospitals.

6. Estimated Effects of Changes to the CMHC CoPs

a. Impacts Related to Conditions of Participation: Admission, Initial Evaluation, Comprehensive Assessment, and Discharge or Transfer of the Client (§ 485.914)

Under the Medicare Program, in accordance with section 4124 of division FF of the CAA. 2023, we propose conforming regulations text changes to establish coverage for Intensive Outpatient Services (IOP) in CMHC at § 485.914 ''Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client''. At § 485.914(a), we require that for clients who are assessed and admitted to receive partial hospitalization services, the CMHC must also meet separate requirements specified in § 485.918(f). In § 418.918(d)(2), we propose to add IOP services to the update of the assessment no less frequently than every 30 days. We do not expect any increase in burden for this modification, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

b. Impacts Related to Conditions of Participation: Treatment Team, Person-Centered Active Treatment Plan, and Coordination of Services (§ 485.916)

This standard requires the active treatment plan to be updated with current information from the client's comprehensive assessment and information concerning the client's progress toward achieving outcomes and goals specified in the active treatment plan. With the addition of IOP services to CMHCs, we believe it is necessary to add IOP into this requirement and to reference the specific IOP program requirements being proposed in section VIII.B.2 at § 424.24(d) of this proposed rule. We do not expect any increase in burden for this modification, nor do we expect the changes for this provision will cause any appreciable expense or anticipated savings. Therefore, we do not believe this standard would impose any additional regulatory burden.

7. Impacts Related to Conditions of Participation: Organization, Governance, Administration of Services, Partial Hospitalization Services (§ 485.918)

The requirement at § 485.918(b) Standard: Provision of services, specifies a comprehensive list of services that a CMHC is required to furnish. This list of services that CMHCs provide corresponds directly to the Statutory requirements in (section 1861(ff)(3) of the Act). We propose to modify the title at § 485.918, by adding intensive outpatient services after partial hospitalization services. In addition, we propose to add IOP to the requirement at § 485.918(b)(1)(iii) for the provision of services. This proposed change will recognize IOP, along with day treatment and PHP, as services that can be provided by a CMHC, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

Lastly, we propose to add a new standard for IOP services at § 485.918(g). This new requirement would specify the additional requirements a CMHC providing IOP services must meet under proposed requirements at § 410.2, § 410.44, § 410.111, and § 424.24(d) of this chapter. We believe that modifying the title of this CoP to include IOP services, as well as adding IOP services to § 485.918(b)(1)(iii) and the proposed new standard at § 485.918(g) will not increase the burden for this modification. In addition, we do not expect the changes to this provision will cause any appreciable amount of expense or anticipated savings, and we do not believe this standard would impose any additional regulatory burden.

8. Effects of Proposals Relating to Hospital Price Transparency

a. Background

Since the hospital price transparency regulation's (at 45 CFR 180) effective date on January 1, 2021, hospitals have been required to make their standard charges available to the public. Various interested parties have reported success in using the data to realize savings. These interested parties come from various parts of the healthcare industry and range from individuals to large organizations. Individual consumers of healthcare have accessed the pricing data to shop for care and save money, and they have created tutorials to teach others how to use this information to achieve similar results.[683] Employers have used the data to reconsider their employee healthcare plans and renegotiate hospital contracts.[684] [685] [686] Innovators have identified and aggregated the data allowing consumers of healthcare to more easily make meaningful comparisons.[687] Insurers have evaluated data, identified hospitals that are cost outliers, and successfully renegotiated their contracts.[688] Researchers [689] and industry experts [690] continue to expose potential savings by publishing on variation in negotiated charges and discounted cash prices for the same items and services both within and across hospitals. Taken together, such actions can motivate hospitals to compete on prices. Furthermore, as interested parties continue to identify new sources of value in this pricing data, the full potential is likely beyond what we previously imagined.

As discussed in more detail in section XVIII of this proposed rule, we believe the revisions we are proposing a number of changes to the hospital price transparency regulations at 45 CFR 180

[683] R&R Insurance. How I Saved Over 1K. Available at: *https://rrins.wistia.com/medias/rkefb7g3aq.*

[684] Minemyer, P. New Playbook Aims to Help Employers, Plan Sponsors Negotiate Hospital Prices. Fierce Healthcare. September 8, 2022. Available at: *https://www.fiercehealthcare.com/payers/new-playbook-aims-help-employers-plan-sponsors-negotiate-hospital-prices.*

[685] Hansard, S. One County Combed Hospital Data to Slash Health Plan Costs 43 percent. Bloomberg. February 6, 2023. Available at: *https://news.bloomberglaw.com/health-law-and-business/employer-health-plan-eyes-43-savings-from-payment-data-audits.*

[686] Hansard, S. Employer, Hospital Tensions Rise Over Price Transparency. Bloomberg. August 2, 2022. Available at: *https://news.bloomberglaw.com/health-law-and-business/tensions-between-employers-hospitals-up-with-transparency-push.*

[687] Turquoise Health. Patients—Shop Healthcare Like You Shop Anything Else. Available at: *https://turquoise.health/patients.*

[688] Pierce, S. Why BlueCross Blue Shield Tennessee is Renegotiating Provider Network Contracts. The Tennessean. August 18, 2022. Available at: *https://www.tennessean.com/story/opinion/2022/08/18/bluecross-blue-shield-tennessee-health-insurance-contracts/10333329002/.*

[689] Mouslim, M., Henderson, M. How New Data on Hospital ''Discounted Cash Prices'' Might Lead to Patient Savings. Health Affairs. November 8, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20211103.716124/full/.*

[690] Smith, C., et al. Hospital Price Transparency Data: Case Studies for How to Use It. Milliman. May 3, 2022. Available at: *https://us.milliman.com/en/insight/hospital-price-transparency-data-case-studies-for-how-to-use-it.*

to accelerate automated aggregation of hospital standard charge information, improve the public's ability to meaningfully understand and use the data, and support and streamline CMS compliance efforts. We propose to: (1) define several new terms; (2) require hospitals to include standard charge information for an increased number of data elements within the MRF and to conform to a CMS template layout data encoding specifications; (3) require hospitals to include a txt file in the root folder that includes a direct link to the MRF and a link in the footer on its homepage that links directly to the publicly available web page that hosts the link to the MRF; and (4) improve our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. Additionally, we are seeking comment on additional considerations for improving compliance and aligning consumer-friendly policies and requirements with other federal price transparency initiatives.

b. Overall Estimated Burden on Hospitals Due to Hospital Price Transparency Requirements

The hospital price transparency proposed policies are estimated to increase burden on hospitals (as defined at 45 CFR 180.20), as detailed in section XXIV ''Collection of Information'', including a one-time cost and increased ongoing costs. However, we believe that the benefits to the public justify this proposed regulatory action.

To analyze the costs of this proposed requirement, we used a baseline that assumes the existing requirements (adopted in the CY 2020 HPT final rule and the CY 2022 OPPS/ASC final rule and codified at 45 CFR 180) remain in place over the time horizon of this RIA. That is, the retrospective analysis and revised cost estimates for recurring administrative burden contained in section XXIV ''Collection of Information'' inform our baseline scenario of no further regulatory action.

As detailed in the Collection of Information section, we estimate a one-time cost for this proposed requirement of approximately $2,787 per hospital, or $19,784,539 ($2,787 × 7,098) for all hospitals combined. To estimate a lower bound of potential burden, we assume hospitals may be sorted into three subsets. First, we note that the proposed MRF templates have been available since November 2022 and a number of hospitals may be already voluntarily meeting these proposed requirements. As a result, a potentially large subset of these hospitals with robust information systems who are fully compliant may only need to review this regulation to ensure that these proposed requirements are being met, which represents our low estimate. A second group of hospitals may have less flexible information systems and limited ability to leverage their existing ad-hoc efforts to adapt to the new requirements; for these hospitals we assume the full collection and implementation cost estimated above. A third subset of hospitals are assumed to not currently be meeting the requirements of existing HPT regulations and would be effectively implementing HPT requirements for the first time. The marginal burden on these hospitals would be limited to the difference in burden under the proposed regulation compared to the existing requirements which the hospital has yet to comply with; we assume the marginal burden to only be 20 percent of the preceding group because these hospitals would have been required to comply with existing regulations regardless of the new proposals. For the low estimate we assume hospitals are distributed 40, 40, and 20 percent across the three subsets described above, respectively. Finally, to account for uncertainty inherent in these types of estimates of administrative costs, we also provide a high estimate which reflects administrative burden 50 percent greater than the primary estimate also detailed in section XXIV ''Collection of Information'' of this proposed rule. These cost range estimates are displayed in Table 106.

TABLE 106: COST RANGE ESTIMATES FOR FIRST YEAR

	Hospitals	Mean Cost / Hospital	Total Cost Burden
Primary Estimate	7,098	$2,787	$19,784,539
High Estimate	7,098	$4,181	$29,676,809
Low Estimate	7,098	$1,274	$9,040,620

In the CY 2020 HPT final rule, we estimated an on-going annual burden of 46 hours per hospital with a cost of $3,610.88 per hospital, resulting in a total national burden of 276,092 hours and total cost of $21,672,502. We anticipate the proposals in this proposed rule would increase hospital annual burden by 8 hours per year, as discussed in greater detail in section XXIV ''Collection of Information'' of this proposed rule. This would result in an increase the total national annual burden to 383,292 hours (54 hours x 7,098 hospitals) and an annual national cost of $32,370,571 dollars ($4,560.52 per respondent x 7,098 hospitals). This represents a $10,698,069 ($32,370,571—$21,672,502) increase over our previous estimated national annual burden for subsequent years.

c. Benefits of Proposals

Although we cannot quantify the benefits of including additional data elements and encoding such data in a CMS template layout, as proposed in this rule, we believe the proposed standardization requirements would help streamline the development and

consumption of the MRF data, making it more actionable for consumers, employers, third party tool developers, and researchers.

(1) Benefits to Hospitals

We believe that requiring the proposed CMS template would assist hospitals with implementing the hospital price transparency regulation and would improve compliance rates, thereby supporting the overarching goal of increasing healthcare pricing competition and lowering costs. As discussed in section XXIV ''Collection of Information'' of this proposed rule, hospitals have sought clarification on how to display their standard charges, particularly payer-specific negotiated charges established by the hospital, and they have indicated that having access to a CMS-developed template could be useful for improving hospital compliance with the HPT regulation.[691] As we noted in section XXIV ''Collection of Information'' of this proposed rule, in response to the CY 2022 OPPS/ASC final rule request for information, hospitals urged CMS to be more prescriptive, requesting that CMS standardize the MRF format and contents. Additionally, researchers and experts suggest that a clear standard format would better support hospital compliance with the regulation.[692] [693] [694] [695] This sentiment was echoed in a Congressional hearing, when witnesses favored a standard template for MRF data, as a means, to support more hospitals complying with the regulation.[696]

(2) Benefits to Other Interested Parties

As discussed in the CY 2020 HPT final rule (84 FR 65538), we believe public access to hospital standard charge information can be useful to the public, including patients who need to obtain items and services from a hospital, consumers of healthcare who wish to view hospital prices prior to selecting a hospital, clinicians who use the data at the point of care when making referrals, employers searching for lower cost options for healthcare coverage, and other users of the data who may develop consumer-friendly price transparency tools or perform analyses to drive value-based policy-development. Since the establishment of the HPT regulation, innovators have made price information accessible to researchers, academics, employers, and the public. Numerous peer-reviewed academic studies have used the MRF data to conduct price analyses.[697] [698] [699] [700] Additionally, journalists and news outlets are now commonly conducting their own price analyses and research with HPT data obtained either directly from the hospital MRF or vendor price estimator tools. For example, some have compared prices of common medical procedures like childbirth, or hip and knee replacements among hospitals within specific regions.[701] [702] Across these publications, authors routinely state that some price comparisons may not be fully accurate due to lack of specificity and standardization of the available hospital MRF data.

Early feedback from interested parties, particularly from IT specialists, researchers, employers, and others who seek to use the standard charge information that hospitals are now required to make public, has indicated that increased standardization may be necessary to improve the public's understanding of the standard charges established by hospitals and the public's ability to make comparisons of standard charges from one hospital to the next. The proposed data elements and CMS templates would not only support hospitals in complying with the rule but also improve the quality and usefulness of MRF data available to consumers of the data, including researchers, innovators, employers, and payers. Studies suggest that standardization would improve the accuracy of price comparisons, the quality and usefulness of MRF data, and perhaps reduce wide variations in hospital prices.[703] [704] In a previous rule, we cited literature regarding consumer engagement with existing price transparency interventions demonstrating that disclosing price information positively impacts consumers of healthcare by allowing them to compare prices for common procedures and shift their demand towards lower-priced options (84 FR 65600). Similarly, studies have indicated that, as these MRF analyses are becoming more widespread, consumers are able to make better use of the pricing information. Standardization would likely remove many of the existing barriers to allow innovators to create more useful data products for consumers of healthcare and reduce some of the uncertainty that currently exists about how hospitals establish standard charges for the items and services they provide.[705]

[691] American Hospital Association. AHA Statement on Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care. March 28, 2023 *https://www.aha.org/testimony/2023-03-28-aha-statement-lowering-unaffordable-costs-examining-transparency-and-competition-health-care.*

[692] The State of Hospital Pricing Transparency in Texas. Texas 2036. Available at: *http://pricetransparency.texas2036.org/.*

[693] Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: *https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023.*

[694] Severn, Chris. Price Transparency Hospital Data: Why Am I Seeing Different Assessments of Hospital Compliance? Turquoise Health. October 18, 2022. Available at: https://blog.turquoise.health/hospital-compliance-assessments/.

[695] Andrews, M. A Progress Check on Hospital Price Transparency. KFF News. March 29, 2023. Available at: *https://kffhealthnews.org/news/article/hospital-price-transparency-federal-rule-checkup-2023/?utm_campaign=KHN%3A%20Daily%20Health%20Policy%20Report&utm_medium=email&_hsmi=252217703&_hsenc=p2ANqtz-9H9illkRczNZhnmE0zhKuwC1oytcDvawv29aM7Fq7gAXWHc_9mjsY3PZkLrJX2vjIDADMQaZ0Yh01jC-NkJqQqflpFlg&utm_content=252217703&utm_source=hs_email.*

[696] ''Lowering Unaffordable Costs: Examining Transparency and Competition in Health Care.'' Congressional House Committee on Energy and Commerce, Subcommittee on Health. March 28, 2023. Available at: https://energycommerce.house.gov/events/health-subcommittee-hearing-lowering-unaffordable-costs-examining-transparency-and-competition-in-health-care

[697] Gul, Z., et al. Large Variations in the Prices of Urologic Procedures at Academic Medical Centers 1 Year After Implementation of the Price Transparency Final Rule. JAMA. January 5, 2023. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088.*

[698] Rochlin, D., et al. Commercial Price Variation for Breast Reconstruction in the Era of Price Transparency. JAMA. December 14, 2022. Available here: *https://jamanetwork.com/journals/jamasurgery/article-abstract/2799698.*

[699] Jiang, X., et al. Price Variability for Common Radiology Services Within U.S. Hospitals. Radiology. October 18, 2022. Available at: *https://pubs.rsna.org/doi/10.1148/radiol.221815.*

[700] Mullens, C., et al. Evaluation of Prices for Surgical Procedures Within and Outside Hospital Networks in the US. JAMA. February 13, 2023. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2801354?utm_source=For_The_Media&utm_medium=referral&utm_campaign=ftm_links&utm_term=021323.*

[701] Maddox, W. How Much Do Insurance Plans Pay for Childbirth in North Texas? D Magazine. April 11, 2023. Available at: *https://www.dmagazine.com/healthcare-business/2023/04/how-much-do-insurance-plans-pay-for-childbirth-in-north-texas/.*

[702] Analysis: Inconsistencies Within Hospital Price Transparency Data Make Costs Comparisons Difficult. KFF. February 10, 2023. Available at: *https://www.kff.org/health-costs/press-release/analysis-inconsistencies-within-hospital-price-transparency-data-make-cost-comparisons-difficult/.*

[703] Lo, J, et al. Ongoing Challenges with Hospital Price Transparency. Peterson-KFF Health System Tracker. February 10, 2023. Available here: *https://www.healthsystemtracker.org/brief/ongoing-challenges-with-hospital-price-transparency/#Select%20data%20for%20University%20of%20Chicago%20Hospitals.*

[704] Hospital Price Transparency: Understanding and Using the Data. National Consumer Law Center. January 25, 2023. Available at: *https://www.nclc.org/event/hospital-pricing-transparency-understanding-and-using-the-data/.*

[705] Severn, Chris. Price Transparency Impact Report Q3 2022. Turquoise Health. October 19, 2022. Available at: *https://s3.us-west-*

Continued

d. Consideration of Increased Burden to Hospitals Due to Hospital Price Transparency Proposals

(1) Proposals Related to MRF Standardization and Accessibility of Hospital MRFs

Many hospitals have expressed concern over two major hurdles in implementing the HPT rule requirements: administrative burden [706] and cost,[707] [708] and we acknowledge that the proposals for increasing the data elements and requiring use of a CMS template would impose an additional one-time burden on hospitals. However, for the reasons discussed in this proposed rule, we believe that transparency is necessary to improve healthcare value, and that the proposals related to MRF standardization would assist hospitals in implementing the HPT regulations and assist numerous interested parties by creating clearer, more accurate data for purposes of price comparison and data analysis that can then be used to drive down healthcare costs. We believe these benefits justify the additional burden to hospitals. We continue to believe that improved hospital compliance with the required disclosure of this pricing information would allow providers, hospitals, insurers, employers, and patients to begin to engage each other and better utilize market forces to address the high cost of healthcare in a more widespread fashion. In addition, we continue to believe, as we noted in the CY 2020 HPT final rule (84 FR 65528), that there is a direct connection between transparency in hospital standard charge information and having more affordable healthcare and lower healthcare costs.

In our CY 2020 HPT final rule, we finalized requirements for MRF accessibility. We prioritized accessibility because we want to be sure hospital standard charge information can be available for use by the public for creating price transparency tools, to be integrated into EHRs for purposes of clinical decision making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare (45 FR 65555). Despite the requirement for the MRF and the standard charge information contained in that file to be digitally searchable and the required naming convention, users of the MRF information, such as IT developers and innovators, continue to express concerns related to challenges in efficiently aggregating the files in an automated way. Some innovators and researchers noted the difficulty in locating hospital MRFs because they are posted on obscure website locations or with links redirecting to vendor websites.[709] [710] We believe that ensuring the MRFs and the data contents are easily accessible to automation aligns with the intended use of the MRFs and their content. Therefore, to increase access to the MRFs, we propose to require hospitals to post a .txt file to the root folder of the public website. To reduce burden on hospitals, CMS would provide both plain language instruction and develop a .txt generator to support this proposed requirement.

As we noted in the preamble, there would be several benefits to requiring a hospital to post a .txt file to the root folder of the public website. This proposed requirement would allow for automated tools to directly link to the MRF, as opposed to the manual location of the correct web page within the website and may make the location of the MRFs more visible to individual consumers who are manually searching for such files. We believe that the benefit of automating the identification of the MRF location would outweigh the minimal burden to maintainers of the public web page that hosts the MRF.

(2) Improvements in CMS Enforcement of Hospital Price Transparency

In the CY 2020 HPT final rule (84 FR 65525), we finalized actions to address hospital noncompliance by requiring hospitals determined by CMS to be in material violation of the HPT regulations to submit a corrective action plan (CAP) and to comply with the requirements of the CAP. For hospitals that fail to respond to or comply with the CAP, CMS may impose CMPs and publicize these penalties on a CMS website. However, there are many nuances and complexities associated with the way hospitals establish standard charges that can lead to questions related to the accuracy and completeness of the standard charges information that is included in a hospital's MRF. As mentioned before, we have found it is necessary to employ methods beyond a simple audit of a hospital's website to definitively assess hospital compliance. Although we expect that the deployment of a standardized MRF template would mitigate many of these questions, we may need additional clarification from the hospital to assess or determine accuracy and completeness of the data. As mentioned above, CMS proposes additional methods to assess compliance which include receiving confirmation of receipt of warning notices directly from individuals at the organization responsible for resolving the deficiencies.

While requiring that hospitals acknowledge receipt of warning notices may require additional effort for hospitals who have received notification of a deficiency, we believe it will streamline our enforcement by providing an appropriate compliance contact earlier in the enforcement process, so that we may provide any necessary technical assistance earlier in the compliance process. We also believe this proposed requirement would provide benefits to others, including consumers, researchers, and innovators, by supporting the public release of standard charge data in a timely and accurate manner.

We do not believe that our compliance activities represent a burden to hospitals and therefore have not included any costs in this burden related to them.

e. Limitations of Our Analysis

It would be difficult for us to conduct a detailed quantitative analysis given the lack of studies at the national level on the regulatory impact of making price transparency information publicly available. Additionally, implementation of the requirements is relatively new, so the impacts may not yet be realized. Finally, several other price transparency initiatives have been implemented, or are in the process of being implemented, that may make a definitive analysis challenging. Since we cannot produce a detailed quantitative analysis, we have developed a qualitative discussion for this regulatory impact analysis, drawing from examples of experiences of the use of public price transparency data that has been released publicly. We have

1.amazonaws.com/assets.turquoise.health/impact_reports/TQ_Price-Transparency-Impact-Report_2022_Q3.pdf.

[706] Kacik, A. Hospital Price Transparency: Fines or Full Compliance? Modern Healthcare. January 24, 2023. Available at: *https://www.modernhealthcare.com/finance/hospital-price-transparency-compliance-cms-deaconess-sanford.*

[707] Jiang, J., et al. Price Transparency in Hospitals-Current Research and Future Directions. JAMA. January 5, 2023. Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2800088.*

[708] Meghjani, T. Lawmakers Question Why Hospital Pricing Isn't Living Up to Transparency Goals. Bloomberg. March 28, 2023. Available at: *https://www.bloomberg.com/news/articles/2023-03-28/what-s-the-best-way-to-compare-hospital-costs-us-hearing-seeks-transparency?leadSource=uverify%20wall#xj4y7vzkg.*

[709] Zuradzki, P. How to Parse Hospital Price Transparency Files. Turquoise Health. October 3, 2022. Available at: *https://blog.turquoise.health/how-to-parse-hospital-price-transparency-files/.*

[710] Fourth Semi-Annual Hospital Price Transparency Report. Patient Rights Advocate. February 14, 2023. Available at: *https://www.patientrightsadvocate.org/february-semi-annual-compliance-report-2023.*

taken an approach that assesses potential directional impact of these proposed requirements (that is, increasing versus decreasing health care costs, increasing, or decreasing likelihood of certain market behaviors) rather than attempting more specific estimates due to the lack of empirical data. We believe there are many benefits with this regulation, particularly to speed the ability of users of the machine-readable files to identify, ingest, analyze and draw more meaningful comparisons of the hospital standard charge data and ultimately for consumers who will be able to benefit from cost savings through employer-payer negotiations, or through direct access to hospital cost comparison data developed by innovators and researchers, allowing the ability to shop for the best value.

f. Alternatives Considered

This proposal is designed to begin to address some of the barriers identified that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs. Specifically, this proposed rule aims to make hospital standard charges more readily available to the public by improving machine-readability of the data and improving automated access to the MRFs. We considered a number of alternative approaches including reducing or increasing the number of proposed data elements, or limiting the CMS template to a single format (for example, JSON).

The proposal to increase data elements that are necessary to provide context to hospital standard charges represents nearly the entire cost in our burden estimate. Thus, reducing the number of proposed data elements would reduce hospital burden and the cost associated with gathering the data necessary to display which increasing the number of proposed data elements would increase hospital burden and the cost associated with gathering data for display. The proposed number of data elements is based on CMS contractor recommendations which took into consideration technical expert input (including input from hospital experts). These technical experts indicated that the data elements currently included in the sample formats found on the CMS website were necessary for providing context to hospital standard charges. They also indicated that the data elements we included in the sample formats strike a balance between burden on the hospital and benefit to the public.

The alternative proposal considered to limit hospital choice of format for the MRF to JSON would be expected to increase hospital burden for hospitals that lack technical expertise.

Ultimately, however, we determined that the alternatives would either limit the usefulness of hospital standard charge information or increase burden for hospitals without any additional benefit to for users of MRF standard charge information.

D. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed or final rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's 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 rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. 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 rule is $123.06 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 would take approximately 8 hours for the staff to review half of this proposed or final rule. For each entity that reviews the rule, the estimated cost is $984.48 (8 hours x $123.06). Therefore, we estimate that the total cost of reviewing this regulation is $1,574,184 ($984.48 x 1,599).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that, many hospitals are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. For details, we refer readers to the Small Business Administration's ''Table of Size Standards'' at *http://www.sba.gov/content/table-small-business-sizestandards.*

Individuals and states are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold will be reached by the requirements in this proposed rule. As a result, the Secretary has determined that this proposed rule may have a significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 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 100 or fewer beds. We estimate that this proposed rule will increase payments to small rural hospitals by approximately 5 percent; therefore, it should have a negligible impact on approximately 555 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act Analysis

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.''

G. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they will not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 100 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.8 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXIII of this proposed rule, this rule should not have a significant effect on small rural hospitals.

H. Conclusion

The changes we propose in this proposed rule will affect all classes of hospitals paid under the OPPS as well as both CMHCs and ASCs. We estimate that most classes of hospitals paid under the OPPS would experience a modest increase or a minimal decrease in payment for services furnished under the OPPS in CY 2024. Table 100 demonstrates the estimated distributional impact of the OPPS budget neutrality requirements that would result in a 2.9 percent increase in payments for all services paid under the OPPS in CY 2024, after considering all of the changes to APC reconfiguration and recalibration, as well as the OPD fee schedule increase factor, wage index changes, including the frontier State wage index adjustment, and estimated payment for outliers, changes to the pass-through payment estimate, and changes to outlier payments. However, some classes of providers that are paid under the OPPS would experience more significant gains or losses in OPPS payments in CY 2024.

The updates we are making to the ASC payment system for CY 2024 will affect each of the approximately 6,000 ASCs currently approved for participation in the Medicare program. The effect on an individual ASC will depend on its mix of patients, the proportion of the ASCs patients who are Medicare beneficiaries, the degree to which the payments for the procedures offered by the ASC are changed under the ASC payment system, and the extent to which the ASC provides a different set of procedures in the coming year than in previous years. Table 101 demonstrates the estimated distributional impact among ASC surgical specialties of the productivity-adjusted hospital market basket update factor of 2.8 percent for CY 2024.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on June 26, 2023.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, and X-rays.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, and Reporting and recordkeeping requirements.

45 CFR Part 180

Hospitals, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b–12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 2. Section 405.2400 is amended by adding paragraph (d) to read as follows:

§ 405.2400 Basis.

* * * * *

(d) Section 1834(y)—Payment for certain services furnished by rural health clinics.

■ 3. Section 405.2401(b) is amended by adding the definition of ''Intensive outpatient services'' in alphabetical order to read as follows:

§ 405.2401 Scope and definitions.

* * * * *

(b) * * *

Intensive outpatient services means a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and that furnishes the services as described in § 410.44 of this chapter.

* * * * *

■ 4. Section 405.2410 is amended by adding paragraph (c) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(c) *Application of deductible and coinsurance for RHCs and FQHCs paid on the basis of the special payment rule described under § 405.2462(j) of this section.* (1) For RHCs, a coinsurance

amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(1) of this part; or

(2) For FQHCs, a coinsurance amount that does not exceed 20 percent of the payment determined under § 405.2462(j)(2).

■ 5. Section 405.2411 is amended by adding paragraph (a)(7) to read as follows:

§ 405.2411 Scope of benefits.

(a) * * *

(7) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

■ 6. Amend § 405.2446 by adding paragraph (b)(10) to read as follows:

§ 405.2446 Scope of services.

* * * * *

(b) * * *

(10) Intensive outpatient services when provided in accordance with section 1861(ff)(4) of the Act and § 410.44 of this chapter.

* * * * *

■ 7. Section 405.2462 is amended by adding paragraph (j) to read as follows:

§ 405.2462 Payment for RHC and FQHC services.

* * * * *

(j) An RHC is paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter. There are no adjustments to this rate.

(1) If the deductible has been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the payment amount determined under paragraph (j)(1) of this section.

(2) If the deductible has not been fully met by the beneficiary prior to the RHC service, Medicare pays eighty (80) percent of the difference between the remaining deductible and the payment amount determined under paragraph (j)(1) of this section; or

(3) If the deductible has not been fully met by the beneficiary prior to the RHC service, no payment is made to the RHC if the deductible is equal to or exceeds the payment amount determined under paragraph (j)(1) of this section.

(4) FQHCs are paid the payment rate determined under § 419.21(a) of this chapter for services described under § 410.44 of this chapter, there are no adjustments to this rate. Except as noted in paragraph (f) of this section.

(i) Medicare pays eighty (80) percent of the lesser of the FQHC's actual charge or the payment rate determined under paragraph (j)(2) of this section; or

(ii) Medicare pays eighty (80) percent of the lesser of a grandfathered tribal FQHC's actual charge or the amount described under paragraphs (f)(2) and (f)(3) of this section.

(iii) No deductible is applicable to FQHC services.

■ 8. Section 405.2463 is amended by revising paragraphs (c)(1)(ii) and (iii), and (c)(4)(ii) to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(c) * * *

(1) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day: or

(iii) Has an initial preventive physical exam visit and a separate medical, mental health, or intensive outpatient services visit on the same day.

* * * * *

(4) * * *

(ii) Has a medical visit and a mental health visit or intensive outpatient services on the same day.

■ 9. Section 405.2464 is amended by adding paragraph (f) to read as follows:

§ 405.2464 Payment rate.

* * * * *

(f) Payment for intensive outpatient services. Payment to RHCs and FQHCs is at the rate determined under § 405.2462(j).

■ 10. Section 405.2468 is amended by adding paragraph (g) to read as follows:

§ 405.2468 Allowable costs.

* * * * *

(g) *Intensive outpatient services.* (1) For RHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for RHC services under the methodology for all-inclusive rates under section 1833(a)(3) of the Act as described in § 405.2464(a).

(2) For FQHCs, costs associated with intensive outpatient services are not used to determine the amount of payment for FQHC services under the prospective payment system under section 1834(o)(2)(B) of the Act as described in § 405.2464(b).

■ 11. Section 405.2469 is amended by revising paragraphs (a)(1) and (a)(2), and adding paragraphs (a)(3) and (b)(4) to read as follows:

§ 405.2469 FQHC supplemental payments.

(a) * * *

(1) The PPS rate if the FQHC is authorized to bill under the PPS;

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs; or

(3) The payment rate as determined in § 405.2462(j).

(b) * * *

(4) Payments received by the FQHC from the MA plan as determined on a per visit basis and the payment rate as determined in § 405.2462(j), less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 12. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, and 1395ddd.

■ 13. Section 410.2 is amended by—

■ a. In the definition r ''Community mental health center (CMHC)'', revise paragraph (3);

■ b. Adding the definition ''Intensive outpatient services'' in alphabetical order; and

■ c. Revising the definition for ''Participating''.

The revisions and addition read as follows:

§ 410.2 Definitions.

* * * * *

Community mental health center (CMHC) means an entity that—

* * * * *

(3) Provides day treatment or other partial hospitalization services or intensive outpatient services, or psychosocial rehabilitation services;

* * * * *

Intensive outpatient services mean a distinct and organized intensive ambulatory treatment program that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting and furnishes the services as described in § 410.44. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization.

* * * * *

Participating refers to a hospital, CAH, SNF, HHA, CORF, or hospice that has in effect an agreement to participate in Medicare; or a clinic, rehabilitation agency, or public health agency that has a provider agreement to participate in Medicare but only for purposes of providing outpatient physical therapy, occupational therapy, or speech pathology services; or a CMHC that has in effect a similar agreement but only for purposes of providing partial hospitalization services and intensive outpatient services, and nonparticipating refers to a hospital,

CAH, SNF, HHA, CORF, hospice, clinic, rehabilitation agency, public health agency, or CMHC that does not have in effect a provider agreement to participate in Medicare.

* * * * *

■ 14. Section 410.3 is amended by revising paragraph (a)(2) to reads as follows:

§ 410.3 Scope of benefits.

(a) * * *

(2) Services furnished by ambulatory surgical centers (ASCs), home health agencies (HHAs), comprehensive outpatient rehabilitation facilities (CORFs), and partial hospitalization services and intensive outpatient services provided by community mental health centers (CMHCs).

* * * * *

■ 15. Section 410.10 is amended by revising paragraph (c) to read as follows:

§ 410.10 Medical and other health services: Included services.

* * * * *

(c) Services and supplies, including partial hospitalization services and intensive outpatient services, that are incident to physician services and are furnished to outpatients by or under arrangements made by a hospital or a CAH.

* * * * *

■ 16. Section 410.27 is amended by revising paragraphs (a)(1)(iv)(B)(1), (a)(2), and (e) introductory text to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

* * * * *

(a) * * *

(1) * * *

(iv) * * *

(B) * * *

(*1*) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. Through December 31, 2024, the presence of the physician or nonphysician practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

(2) In the case of partial hospitalization services or intensive outpatient services, also meet the conditions of paragraph (e) of this section.

* * * * *

(e) Medicare Part B pays for partial hospitalization services and intensive outpatient services if they are—

* * * * *

■ 17. Section 410.44 is added to read as follows:

§ 410.44 Intensive outpatient services: Conditions and exclusions.

(a) Intensive outpatient services are services that—

(1) Are reasonable and necessary for the diagnosis or active treatment of the individual's condition;

(2) Are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization;

(3) Are furnished in accordance with a physician certification and plan of care as specified under § 424.24(d) of this chapter; and

(4) Include any of the following:

(i) Individual and group therapy with physicians or psychologists or other mental health professionals to the extent authorized under State law.

(ii) Occupational therapy requiring the skills of a qualified occupational therapist, provided by an occupational therapist, or under appropriate supervision of a qualified occupational therapist by an occupational therapy assistant as specified in part 484 of this chapter.

(iii) Services of social workers, trained psychiatric nurses, and other staff trained to work with psychiatric patients.

(iv) Drugs and biologicals furnished for therapeutic purposes, subject to the limitations specified in § 410.29.

(v) Individualized activity therapies that are not primarily recreational or diversionary.

(vi) Family counseling, the primary purpose of which is treatment of the individual's condition.

(vii) Patient training and education, to the extent the training and educational activities are closely and clearly related to the individual's care and treatment.

(viii) Diagnostic services.

(b) The following services are separately covered and not paid as intensive outpatient services:

(1) Physician services that meet the requirements of § 415.102(a) of this chapter for payment on a fee schedule basis.

(2) Physician assistant services, as defined in section 1861(s)(2)(K)(i) of the Act.

(3) Nurse practitioner and clinical nurse specialist services, as defined in section 1861(s)(2)(K)(ii) of the Act.

(4) Qualified psychologist services, as defined in section 1861(ii) of the Act.

(5) Services furnished to SNF residents as defined in § 411.15(p) of this chapter.

(c) Intensive outpatient programs are intended for patients who -

(1) Require a minimum of 9 hours per week of therapeutic services as evidenced in their plan of care;

(2) Are likely to benefit from a coordinated program of services and require more than isolated sessions of outpatient treatment;

(3) Do not require 24-hour care;

(4) Have an adequate support system while not actively engaged in the program;

(5) Have a mental health diagnosis;

(6) Are not judged to be dangerous to self or others; and

(7) Have the cognitive and emotional ability to participate in the active treatment process and can tolerate the intensity of the intensive outpatient program.

■ 18. Section 410.67 is amended by—

■ a. In paragraph (b), amend the definition of ''*Opioid use disorder treatment service*'' by adding paragraph (ix);

■ b. Adding paragraph (c)(5);

■ d. Revising paragraph (d)(3);

■ e. Adding (d)(4)(i)(F); and

■ f. Revising paragraphs (d)(4)(ii) and (iii).

The revisions and additions read as follows:

§ 410.67 Medicare coverage and payment of Opioid use disorder treatment services furnished by Opioid treatment programs.

* * * * *

(b) * * *

(ix) OTP intensive outpatient services, which means one or more services specified in § 410.44(a)(4) when furnished by an OTP as part of a distinct and organized intensive ambulatory treatment program for the treatment of Opioid Use Disorder and that offers less than 24-hour daily care other than in an individual's home or in an inpatient or residential setting. OTP intensive outpatient services are reasonable and necessary for the diagnosis or active treatment of the individual's condition; are reasonably expected to improve or maintain the individual's condition and functional level and to prevent relapse or hospitalization; and are furnished in

accordance with a physician certification and plan of care, in which a physician must certify that the individual has a need for a minimum of nine hours of services per week and requires a higher level of care intensity compared to other non-intensive outpatient OTP services. OTP intensive outpatient services do not include FDA-approved opioid agonist or antagonist medications for the treatment of OUD, opioid antagonist medications for the emergency treatment of known or suspected opioid overdose, or toxicology testing.

* * * * *

(c) * * *

(5) OTPs that provide OTP intensive outpatient services must meet the requirements set forth in § 424.24(d)(1) through (3) of this chapter related to content of certification, plan of treatment, and recertification for the purposes of furnishing OTP intensive outpatient services, except that the recertification required under § 424.24(d)(3)(ii) of this chapter may occur any time during an episode of care in which the 30th day from the start of IOP services falls.

* * * * *

(d) * * *

(3) At least one OUD treatment service described in paragraphs (i) through (v) of the definition of Opioid use disorder treatment service in paragraph (b) of this section must be furnished to bill for the bundled payment for an episode of care.

(4) * * *

(i) * * *

(F) For OTP intensive outpatient services, an adjustment will be made when at least nine OTP intensive outpatient services described in paragraph (b)(ix) of this section are furnished in a week. This adjustment will be based on the per diem payment rate for intensive outpatient services at hospital-based programs defined at 410.44(c) and multiplied by a factor of three for a weekly payment adjustment, excluding an amount equivalent to the amount included in the OTP weekly bundled payment for individual and group therapy.

(ii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments, and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be geographically adjusted using the Geographic Adjustment Factor described in § 414.26 of this subchapter. For purposes of this adjustment, OUD treatment services that are furnished via an OTP mobile unit will be treated as if they were furnished at the physical location of the OTP registered with the Drug Enforcement Administration (DEA) and certified by SAMHSA.

(iii) The payment amounts for the non-drug component of the bundled payment for an episode of care, the adjustments for counseling or therapy, intake activities, periodic assessments and OTP intensive outpatient services, and the non-drug component of the adjustment for take-home supplies of opioid antagonist medications will be updated annually using the Medicare Economic Index described in § 405.504(d) of this subchapter.

* * * * *

■ 19. Revise the heading to Subpart E to read as follows:

Subpart E—Community Mental Health Centers (CMHCs) Providing Partial Hospitalization Services and Intensive Outpatient Services

■ 20. Section 410.111 is added to read as follows:

§ 410.111 Requirements for coverage of intensive outpatient services in CMHCs.

Medicare part B covers intensive outpatient services furnished by or under arrangements made by a CMHC if they are provided by a CMHC as defined in § 410.2 that has in effect a provider agreement under part 489 of this chapter and if the services are—

(a) Prescribed by a physician and furnished under the general supervision of a physician;

(b) Subject to certification by a physician in accordance with § 424.24(d)(1) of this subchapter; and

(c) Furnished under a plan of treatment that meets the requirements of § 424.24(d)(2) of this subchapter.

■ 21. Section 410.150 is amended by revising paragraph (b)(13) to read as follows:

§ 410.150 To whom payment is made.

* * * * *

(b) * * *

(13) To a community mental health center (CMHC) on the individual's behalf, for partial hospitalization services or intensive outpatient services furnished by the CMHC (or by others under arrangements made with them by the CMHC).

* * * * *

■ 22. Section 410.155 is amended by revising paragraph (b)(2)(iii) to read as follows:

§ 410.155 Outpatient mental health treatment limitation.

* * * * *

(b) * * *

(2) * * *

(iii) Partial hospitalization services or intensive outpatient services not directly provided by a physician.

* * * * *

■ 23. Section 410.173 is added to read as follows:

§ 410.173 Payment for intensive outpatient services in CMHCs: Conditions.

Medicare Part B pays for intensive outpatient services furnished in a CMHC on behalf of an individual only if the following conditions are met:

(a) The CMHC files a written request for payment on the CMS form 1450 and in the manner prescribed by CMS; and

(b) The services are furnished in accordance with the requirements described in § 410.111.

PART 416—AMBULATORY SURGICAL SERVICES

■ 24. The authority citation for part 416 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 25. Section 416.171 is amended by revising paragraphs (a)(2)(iii), (iv), (vi), and (vii), and (a)(2)(viii)(B) and (C) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2025, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2026 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

* * * * *

(vi) For CY 2019 through CY 2025, the hospital inpatient market basket update determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii) * * *

(B) For CY 2019 through CY 2025, the hospital inpatient market basket update

determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(vi) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2026 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

■ 26. Section 416.172 is amended by revising paragraph (d) to read as follows:

§ 416.172 Adjustments to national payment rates.

* * * * *

(d) *Deductibles and coinsurance.* Part B deductible and coinsurance amounts apply as specified in §§ 410.152(a) and (i)(2) of this subchapter and in 42 CFR 489.30(b)(6).

* * * * *

■ 27. Section 416.305 is amended by revising paragraph (b)(1) to read as follows:

§ 416.305 Participation and withdrawal requirements under the ASCQR Program.

* * * * *

(b) * * *

(1) An ASC may withdraw from the ASCQR Program by submitting to CMS a withdrawal of participation form that can be found in the secure portion of the CMS-designated information system.

* * * * *

■ 28. Section 416.310 is amended by revising paragraphs (c)(1)(i) and (d)(1) to read as follows:

§ 416.310 Data collection and submission requirements under the ASQR Program.

* * * * *

(c) * * *

(1) * * *

(i) CMS-designated information system account for web-based measures. ASCs, and any agents submitting data on an ASC's behalf, must maintain an account for the CMS-designated information system in order to submit quality measure data to the CMS-designated information system for all web-based measures submitted via a CMS online data submission tool. A security official is necessary to set up such an account for the CMS-designated information system for the purpose of submitting this information.

* * * * *

(d) * * *

(1) *Upon request of the ASC.* Specific requirements for submission of a request for an exception are available on the CMS website.

* * * * *

■ 29. Section 416.320 is amended by revising paragraph (b) to read as follows:

§ 416.320 Retention and removal of quality measures under the ASCQR Program.

* * * * *

(b) *Immediate measure removal.* In cases where CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the ASCQR Program and will promptly notify ASCs and the public of the removal of the measure and the reasons for its removal through the ASCQR Program ListServ and the ASCQR Program CMS website. CMS will confirm the removal of the measure for patient safety concerns in the next ASCQR Program rulemaking.

* * * * *

■ 30. Section 416.325 is amended by revising paragraph (c) to read as follows:

§ 416.325 Measure maintenance under the ASCQR Program.

* * * * *

(c) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the ASCQR Program is non-substantive, CMS will use a sub-regulatory process to revise the ASCQR Program Specifications Manual so that it clearly identifies the changes to that measure and provide links to where additional information on the changes can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on the CMS website and in the ASCQR Program Specifications Manual, and will provide sufficient lead time for ASCs to implement the revisions where changes to the data collection systems would be necessary.

PART 419—PROSPECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 31. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 32. Section 419.20 is amended by adding paragraph (b)(5) to read as follows:

§ 419.20 Hospitals subject to the hospital outpatient prospective payment system.

* * * * *

(b) * * *

(5) A rural emergency hospital (REH).

■ 33. Section 419.21 is amended by revising paragraph (c) for read as follows:

§ 419.21 Hospital services subject to the outpatient prospective payment system.

* * * * *

(c) Partial hospitalization services and intensive outpatient services furnished by community mental health centers (CMHCs).

* * * * *

■ 34. Section 419.41 is amended by adding paragraphs (d), (e), (f), and (g) to read as follows:

§ 419.41 Calculation of national beneficiary copayment amounts and national Medicare program payment amounts.

* * * * *

(d) Notwithstanding the foregoing, for a drug or biological for which payment is not packaged into a payment for a covered OPD service (or group of services) and is not a rebatable drug (as defined in section 1847A(i)(2)(A)), to calculate the program payment and copayment amounts CMS does the following:

(1) Determines the payment rate for the drug or biological for the quarter established under the methodology described by section 1842(o), section 1847A, or section 1847B of the Act, as the case may be, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14) of section 1833(t) of the Act.

(2) Subtracts from the amount determined under paragraph (d)(1) of this section the amount of the applicable Part B deductible provided under § 410.160 of this chapter.

(3) Multiples the amount determined under paragraph (d)(1) of this section (less any applicable deductible under paragraph (d)(2) of this section) by 20 percent. This is the beneficiary's copayment amount for the drug or biological.

(4) Subtracts the amount determined under paragraph (d)(3) of this section from the amount determined under paragraph (d)(1) of this section (less any applicable deductible determined under paragraph (d)(2) of this section). This amount is the preliminary program amount.

(5) Adds to the preliminary program amount determined under paragraph (d)(4) of this section the amount by which the copayment amount would have exceeded the inpatient hospital deductible for that year. This amount is the final Medicare program payment amount.

(e) In the case of a rebatable drug (as defined in section 1847A(i)(2)(A) of the

Act), except if such drug does not have a copayment amount as a result of application of section 1833(t)(8)(E) of the Act, for which payment is not packaged into payment for a covered OPD service (or group of services) furnished on or after April 1, 2023, and the payment for such drug under the OPPS is the same as the amount for a calendar quarter under section 1847A(i)(3)(A)(ii)(I) of the Act, in lieu of the calculation of the copayment amount and the Medicare program payment amount otherwise applicable under paragraph (d) of this section (other than application of the limitation described in paragraph (c)(4)(i) of this section), the copayment and Medicare program payment amounts determined under §§ 410.152(m) and 489.30(b)(6) of this chapter shall apply.

(f) In the case of a qualifying biosimilar biological product (as defined in § 414.902 of this subchapter) that is furnished during the applicable five-year period (as defined in § 414.902 of this subchapter) for such product, the payment amount for such product with respect to such period is the amount determined in § 414.904(j)(2) of this subchapter.

(g) For dates of service on or after July 1, 2024, the payment amount for a biosimilar biological product (as defined in § 414.902 of this subchapter) during the initial period is the amount determined in § 414.904(e)(4)(ii) of this subchapter.

■ 35. Section 419.46 is amended by revising the section heading and paragraphs (b), (c), (d)(2), (e)(1), (g)(1), and (i)(2) to read as follows:

§ 419.46 Requirements Under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(b) *Participation in the Hospital OQR Program.* To participate in the Hospital OQR Program, a hospital as defined in section 1886(d)(1)(B) of the Act and is paid under the OPPS must—

(1) Register on the CMS-designated information system before beginning to report data;

(2) Identify and register a CMS-designated information system security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit at least one data element.

(c) *Withdrawal from the Hospital OQR Program.* A participating hospital may withdraw from the Hospital OQR Program by submitting to CMS a withdrawal form that can be found in the secure portion of the CMS-designated information system. The hospital may withdraw any time up to and including August 31 of the year prior to the affected annual payment updates. A withdrawn hospital will not be able to later sign up to participate in that payment update, is subject to a reduced annual payment update as specified under paragraph (i) of this section, and is required to renew participation as specified in paragraph (b) of this section in order to participate in any future year of the Hospital OQR Program.

(d) * * *

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on the CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or Executive order.

* * * * *

(e) * * *

(1) *Upon request by the hospital.* Specific requirements for submission of a request for an exception are available on the CMS website.

* * * * *

(g) * * *

(1) A hospital may request reconsideration of a decision by CMS that the hospital has not met the requirements of the Hospital OQR Program in paragraph (b) of this section for a particular calendar year. Except as provided in paragraph (e) of this section, a hospital must submit a reconsideration request to CMS via the CMS-designated information system, no later than March 17, or if March 17 falls on a nonwork day, on the first day after March 17 which is not a nonwork day as defined in paragraph (d)(2) of this section, of the affected payment year as determined using the date the request was mailed or submitted to CMS.

* * * * *

(i) * * *

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure as specified raises patient safety concerns, CMS will immediately remove a quality measure from the Hospital OQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital OQR Program ListServ and the CMS website.

* * * * *

■ 36. Section 419.92 is amended by adding paragraphs (d) and (e) to read as follows:

§ 419.92 Payment to rural emergency hospitals.

* * * * *

(d) *Payment for IHS or tribally operated REHs.* An Indian Health Service (IHS) or tribally operated REH, as defined in paragraph (e) of this section will be paid under the outpatient hospital All-Inclusive Rate that is established and published annually by the Indian Health Service rather than the rates for REH services described in paragraph (a)(1) of this section.

(e) *IHS or tribally operated REHs.* An Indian Health Service (IHS) or tribally operated REH is an REH, as defined in § 485.502 of this chapter, that is operated by the IHS or by a tribe or tribal organization with funding authorized by Title I or III of the Indian Self-Determination and Education Assistance Act (Pub. L. 93–638).

■ 37. Section 419.93 is amended by revising paragraph (a)(2) to read as follows:

§ 419.93 Payment for an off-campus provider-based department of a rural emergency hospital.

(a) * * *

(2) Services that do not meet the definition of REH services under § 419.91 that are furnished by an off-campus provider-based department of an REH are paid as described under § 419.92(c) or, if applicable, § 419.92(d).

* * * * *

■ 38. Section 419.95 is added to read as follows:

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

(a) *Statutory authority.* Section 1861(kkk) (7) of the Social Security Act authorizes the Secretary to implement a quality reporting program requiring Rural Emergency Hospitals (REHs) to submit data on measures in accordance with the Secretary's requirements in this part.

(b) *Participation in the REHQR Program.* To participate in the REHQR Program, an REH as defined in section 1861(kkk) (2) of the Act must—

(1) Register on a CMS website before beginning to report data;

(2) Identify and register a security official as part of the registration process under paragraph (b)(1) of this section; and

(3) Submit data on all quality measures to CMS as specified under paragraph (d) of this section.

(c) *Submission of REHQR Program data*—(1) *General rule.* REHs that participate in the REHQR Program must submit to CMS data on measures selected under section 1861(kkk)(7)(C) of the Act in a form and manner, and at a time specified by CMS. REHs sharing the same CMS Certification Number (CCN) must combine data collection and submission across their multiple campuses for all clinical measures for public reporting purposes.

(2) *Submission deadlines.* Submission deadlines by measure and by data type are posted on a CMS website. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-work day for Federal employees by statute or executive order are extended to the first day thereafter which is not a Saturday, Sunday, or legal holiday or any other day all or part of which is declared to be a non-work day for Federal employees by statute or executive order.

(3) *Review and corrections period.* For all quality data submitted, REHs will have a review and corrections period, which runs concurrently with the data submission period. During this timeframe, REHs can enter, review, and correct data submitted. However, after the submission deadline, these data cannot be changed.

(d) *Technical specifications and measure maintenance under the REHQR Program.*

(1) CMS will update the specifications manual for measures in the REHQR Program at least every 12 months.

(2) CMS follows different procedures to update the measure specifications of a measure previously adopted under the REHQR Program based on whether the change is substantive or non-substantive. CMS will determine what constitutes a substantive versus a non-substantive change to a measure's specifications.

(i) *Substantive changes.* CMS will use rulemaking to adopt substantive updates to measures in the REHQR Program.

(ii) *Non-substantive changes.* If CMS determines that a change to a measure previously adopted in the REHQR Program is non-substantive, CMS will use a sub-regulatory process to revise the specifications manual for the REHQR Program so that it clearly identifies the change to that measure and provide links to where additional information on the change can be found. When a measure undergoes sub-regulatory maintenance, CMS will provide notification of the measure specification update on a designated website and in the specifications manual, and will provide sufficient lead time for REHs to implement the revisions where changes to the data collection systems would be necessary.

(e) *Retention and removal of quality measures under the REHQR Program.*

(1) *General rule for the retention of quality measures.* Quality measures adopted for the REHQR Program measure set are retained for use, except when they are removed, suspended, or replaced as set forth in paragraphs (e)(2) and (e)(3) of this section.

(2) *Immediate measure removal.* In cases where CMS believes that the continued use of a quality measure as specified raises patient safety concerns, CMS will immediately remove the measure from the REHQR Program and will promptly notify REHs and the public of the removal of the measure and the reasons for its removal. CMS will confirm the removal of the measure in the next appropriate rulemaking.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (e)(2) of this section, CMS will use rulemaking to remove, suspend, or replace quality measures in the REHQR Program.

(i) *Factors for consideration for removal of quality measures. CMS will weigh whether to remove measures based on the following factors:*

(A) *Factor 1.* Measure performance among REHs is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped-out'' measures);

(B) *Factor 2.* Performance or improvement on a measure does not result in better patient outcomes;

(C) *Factor 3.* A measure does not align with current clinical guidelines or practice;

(D) *Factor 4.* The availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic;

(E) *Factor 5.* The availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;

(F) *Factor 6.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic;

(G) *Factor 7.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm; and

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the REHQR Program, a measure is considered to be topped-out under paragraph (e)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for an REH's measure is within two times the standard error of the full data set); and

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the REHQR Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(f) *Public reporting of data under the REHQR Program.* Data that an REH submits for the REHQR Program will be made publicly available on a CMS website in an easily understandable format after providing the REH an opportunity to review the data to be made public. CMS will publicly display REH data by the CCN when data are submitted under the CCNs.

(g) *Exception.* CMS may grant an exception to one or more data submission deadlines and requirements in the event of extraordinary circumstances beyond the control of the hospital, such as when an act of nature affects an entire region or locale or a systemic problem with one of CMS' data collection systems directly or indirectly affects data submission. CMS may grant an exception as follows:

(1) *Upon request by the REH.* Specific requirements for submission of a request for an exception are available on a CMS website.

(2) *At the discretion of CMS.* CMS may grant exceptions to REHs that have not requested them when CMS determines that an extraordinary circumstance has occurred.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 39. The authority citation for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 40. Section 424.24 is amended by—
■ a. Revising paragraphs (b);
■ b. Adding paragraph (d), and
■ c. Revising paragraph (e)(1)(i).

The revisions and addition read as follows:

§ 424.24 Requirements for medical and other health services furnished by providers under Medicare Part B.

* * * * *

(b) *General rule.* Medicare Part B pays for medical and other health services

furnished by providers (and not exempted under paragraph (a) of this section) only if a physician certifies the content specified in paragraphs (c)(1), (c)(4), (d)(1), or (e)(1) of this section, as appropriate.

* * * * *

(d) *Intensive outpatient services: Content of certification and plan of treatment requirements*—

(1) *Content of certification.* (i) The individual requires such services for a minimum of 9 hours per week.

(ii) The services are or were furnished while the individual was under the care of a physician.

(iii) The services were furnished under a written plan of treatment that meets the requirements of paragraph (d)(2) of this section.

(2) *Plan of treatment requirements.* (i) The plan is an individualized plan that is established and is periodically reviewed by a physician in consultation with appropriate staff participating in the program, and that sets forth—

(A) The physician's diagnosis;

(B) The type, amount, duration, and frequency of the services; and

(C) The treatment goals under the plan.

(ii) The physician determines the frequency and duration of the services taking into account accepted norms of medical practice and a reasonable expectation of improvement in the patient's condition.

(3) *Recertification requirements*—(i) Signature. The physician recertification must be signed by a physician who is treating the patient and has knowledge of the patient's response to treatment.

(ii) *Timing.* Recertifications are required at intervals established by the provider, but no less frequently than every 60 days.

(iii) *Content.* The recertification must specify that the patient continues to require at least 9 hours of intensive outpatient services and describe the following:

(A) The patient's response to the therapeutic interventions provided by the intensive outpatient program.

(B) The patient's psychiatric symptoms that continue to place the patient at risk of relapse or hospitalization.

(C) Treatment goals for coordination of services to facilitate discharge from the intensive outpatient program.

(e) * * *

(1) * * *

(i) The individual requires such services for a minimum of 20 hours per week, and would require inpatient psychiatric care if the partial hospitalization services were not provided.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 41. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

■ 42. Section 485.506 is amended by revising paragraphs (b) and (c) to read as follows:

§ 485.506 Designation and certification of REHs.

* * * * *

(b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1886(d)(2)(D) of the Act); or

(c) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

■ 43. Section 485.900 is amended by revising paragraphs (a)(1), (2), and (3) to read as follows:

§ 485.900 Basis and scope.

(a) * * *

(1) Section 1832(a)(2)(J) of the Act specifies that payments may be made under Medicare Part B for partial hospitalization services and intensive outpatient services furnished by a community mental health center (CMHC) as described in section 1861(ff)(3)(B) of the Act.

(2) Section 1861(ff) of the Act describes the items and services that are covered under Medicare Part B as ''partial hospitalization services'' and ''intensive outpatient services'' and the conditions under which the items and services must be provided. In addition, section 1861(ff) of the Act specifies that the entities authorized to provide partial hospitalization services and intensive outpatient services under Medicare Part B include CMHCs and defines that term.

(3) Section 1866(e)(2) of the Act specifies that a provider of services for purposes of provider agreement requirements includes a CMHC as defined in section 1861(ff)(3)(B) of the Act, but only with respect to providing partial hospitalization services and intensive outpatient services.

* * * * *

■ 44. Section 485.904 is amended by revising paragraph (b)(5) and adding paragraph (b)(12) to read as follows:

§ 485.904 Condition of participation: Personnel qualifications.

* * * * *

(b) * * *

(5) *Mental health counselor.* An individual who meets the applicable education, training, and other requirements of § 410.54 of this chapter.

* * * * *

(12) *Marriage and family therapist.* An individual who meets the applicable education, training, and other requirements of § 410.53 of this chapter.

* * * * *

■ 45. Section 485.914 is amended by revising paragraphs (a)(2) and (d)(2) to read as follows:

§ 485.914 Condition of participation: Admission, initial evaluation, comprehensive assessment, and discharge or transfer of the client.

(a) * * *

(2) For clients assessed and admitted to receive partial hospitalization services and intensive outpatient services, the CMHC must also meet separate requirements as specified in §§ 485.918(f) and 485.918(g), as applicable.

* * * * *

(d) * * *

(2) For clients that receive PHP or IOP services, the assessment must be updated no less frequently than every 30 days.

* * * * *

■ 46. Section 485.916 is amended by revising paragraph (d) to read as follows:

§ 485.916 Condition of participation: Treatment team, person-centered active treatment plan, and coordination of services.

* * * * *

(d) *Standard: Review of the person-centered active treatment plan.* The CMHC interdisciplinary treatment team must review, revise, and document the individualized active treatment plan as frequently as the client's condition requires, but no less frequently than every 30-calendar day. A revised active treatment plan must include information from the client's initial evaluation and comprehensive assessments, the client's progress toward outcomes and goals specified in the active treatment plan, and changes in the client's goals. The CMHC must also meet partial hospitalization program requirements specified under § 424.24(e) of this chapter or intensive outpatient service requirements as specified under § 424.24(d) of this chapter, as applicable, if such services

are included in the active treatment plan.

* * * * *

■ 47. Section 485.918 is amended by:
■ a. Revising the section heading;
■ b. Revising paragraph (b)(1)(iii);
■ c. Redesignating paragraph (g) as paragraph (h); and
■ d. Adding paragraph (g).

The revisions and addition read as follows:

§ 485.918 Condition of participation: Organization, governance, administration of services, partial hospitalization services and intensive outpatient services.

* * * * *

(b) * * *

(1) * * *

(iii) Provides day treatment, partial hospitalization services, or intensive outpatient services, other than in an individual's home or in an inpatient or residential setting, or psychosocial rehabilitation services.

* * * * *

(g) *Standard: Intensive outpatient services.* A CMHC providing intensive outpatient services must—

(1) Provide services as defined in § 410.2 of this chapter.

(2) Provide the services and meet the requirements specified in § 410.44 of this chapter.

(3) Meet the requirements for coverage as described in § 410.111 of this chapter.

(4) Meet the content of certification and plan of treatment requirements as described in § 424.24(d) of this chapter.

* * * * *

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 48. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302; and 1395hh.

■ 49. Section 488.2 is amended by revising provision ''1832(a)(2)(J)'' to read as follows:

§ 488.2 Statutory basis.

* * * * *

1832(a)(2)(J)—Requirements for partial hospitalization services and intensive outpatient services provided by CMHCs.

* * * * *

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 50. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395(hh).

■ 48. Section 489.2 is amended by revising paragraph (c)(2) to read as follows:

§ 489.2 Scope of part.

* * * * *

(c) * * *

(2) CMHCs may enter into provider agreements only to furnish partial hospitalization services and intensive outpatient services.

* * * * *

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

■ 51. The authority citation for part 180 continues to read as follows:

Authority: 42 U.S.C. 300gg–18, 42 U.S.C. 1302.

■ 52. Section 180.20 is amended by—
■ a. Adding definitions for ''CMS template'', ''Consumer-friendly expected allowed charges'', ''Encode'', and ''Machine-readable file''.
■ b. In the definition ''Machine-readable format'' removing the sentence ''Examples of machine-readable formats include, but are not limited to, XML, JSON and .CSV formats.''

The additions read as follows:

§ 180.20 Definitions.

* * * * *

CMS template means a CSV format or JSON schema that CMS makes available for purposes of compliance with 180.40(a).

Consumer-friendly expected allowed amount means the average dollar amount that the hospital estimates it will be paid by a third party payer for an item or service.

* * * * *

Encode means to enter data items into the fields of the CMS template.

* * * * *

Machine-readable file means a single digital file that is in a machine-readable format.

* * * * *

■ 53. Section 180.50 is amended by—
■ a. Adding paragraph (a)(3);
■ b. Revising paragraphs (b) and (c);
■ c. Amending paragraph (d)(4) by removing the phrase ''The digital file and standard charge information contained in that file must be'' and adding in its place the phrase ''The machine-readable file and standard charge information contained in that machine-readable file must be''.
■ d. Amending paragraph (d)(5) by:
■ i. Removing the phrase ''The file must'' and adding in its place the phrase ''The machine-readable file must''; and
■ ii. Removing the phrase ''[json|xml|csv]'' and adding in its place the phrase ''[json|csv]''.
■ e. Adding paragraph (d)(6).
■ f. Amending paragraph (e) by removing the second sentence.

The additions and revisions read as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

* * * * *

(a) * * *

(3) The hospital must include a statement in its machine-readable file affirming that the hospital, to the best of its knowledge and belief, has included all applicable standard charge information in accordance with the requirements of this section, and that the information displayed is true, accurate, and complete as of the date indicated in the file.

(b) *Required data elements.* Each hospital must encode in its machine-readable file all standard charge information, as applicable, for each of the following required data elements:

(1) General data elements:

(i) Hospital name, license number, and location name(s) and address(es) at which the public may obtain the items and service at the standard charge amount indicated in the machine-readable file; and

(ii) The version number of the CMS template and the date of most recent update of the standard charge information in the machine-readable file.

(2) Each type of standard charge as defined at § 180.20 (for example, gross charge, discounted cash price, payer-specific negotiated charge, de-identified minimum negotiated charge, and de-identified maximum negotiated charge) and, for payer-specific negotiated charges, the following additional data elements:

(i) Payer and plan names; plan(s) may be indicated as categories (such as ''all PPO plans'') when the established payer-specific negotiated charges are applicable to each plan in the indicated category.

(ii) Type of contracting method used to establish the standard charge; and

(iii) Whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard charge is based on a percentage or algorithm. If the standard charge is based on a percentage or algorithm, the MRF must also specify what percentage or algorithm determines the dollar amount for the item or service, and the consumer-friendly expected allowed amount for that item or service.

(3) A description of the item or service that corresponds to the standard charge established by hospital, including:

(i) A general description of the item or service;

(ii) Whether the item or service is provided in connection with an inpatient admission or an outpatient department visit; and

(iii) For drugs, the drug unit and type of measurement.

(4) Any codes used by the hospital for purposes of accounting or billing for the item or service, modifier(s), and the code type(s).

(c) *Format.* The hospital's machine-readable file must conform to the CMS template layout, data specifications, and data dictionary for purposes of making public the standard charge information required under paragraph (b) of this section.

(d) * * *

(6) The hospital must ensure that the public website it selects to host its machine-readable file establishes and maintains, in the form and manner specified by CMS:

(i) A .txt file in the root folder that includes:

(A) The hospital location name that corresponds to the machine-readable file;

(B) The source page URL that hosts the machine-readable file;

(C) A direct link to the machine-readable file (the machine-readable file URL); and

(D) Hospital point of contact information.

(ii) A link in the footer on its website, including but not limited to the homepage, that is labeled ''Hospital Price Transparency'' and links directly to the publicly available web page that hosts the link to the machine-readable file.

■ 54. Section 180.70 is amended by:

■ a. Revising paragraph (a) introductory text.

■ b. Revising paragraph (a)(2)(iii).

■ c. By adding paragraphs (a)(2)(iv) and (v).

■ d. By revising paragraph (b)(1); and

■ e. By adding paragraphs (c) and (d).

The additions and revisions read as follows:

§ 180.70 Monitoring and enforcement.

(a) *Monitoring and assessment.*

(1) * * *

(2) * * *

* * * * *

(iii) CMS audit and comprehensive review.

(iv) Requiring submission of certification by an authorized hospital official as to the accuracy and completeness of the data in the machine-readable file.

(v) Requiring submission of additional documentation as may be necessary to make a determination of hospital compliance.

(b) * * *

(1) Provide a written warning notice to the hospital of the specific violation(s). CMS will require that a hospital submit an acknowledgement of receipt of the warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital.

* * * * *

(c) *Actions to address noncompliance of hospitals in health systems.* In the event CMS takes an action to address hospital noncompliance (as specified in paragraph (b) of this section) and the hospital is determined by CMS to be part of a health system, CMS may notify health system leadership of the action and may work with health system leadership to address similar deficiencies for hospitals across the health system.

(d) *Publicizing assessments, compliance actions, and outcomes.* CMS may publicize on its website information related to the following:

(1) CMS' assessment of a hospital's compliance.

(2) Any compliance action taken against a hospital, the status of such compliance action, or the outcome of such compliance action.

(3) Notifications sent to health system leadership.

§ 180.90 [Amended]

■ 55. In § 180.90, amend paragraph (b)(2)(ii)(C) by removing the phrase ''resulting from monitoring activities'' and adding in its place the phrase ''resulting from monitoring and assessment activities''.

Dated: July 7, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–14768 Filed 7–13–23; 4:15 pm]

BILLING CODE 4120–01–P

FEDERAL REGISTER

Vol. 88 Monday,

No. 145 July 31, 2023

Part III

Council on Environmental Quality

40 CFR Parts 1500, 1501, 1502, et al.
National Environmental Policy Act Implementing Regulations Revisions Phase 2; Proposed Rule

COUNCIL ON ENVIRONMENTAL QUALITY

40 CFR Parts 1500, 1501, 1502, 1503, 1504, 1505, 1506, 1507, and 1508

[CEQ–2023–0003]

RIN 0331–AA07

National Environmental Policy Act Implementing Regulations Revisions Phase 2

AGENCY: Council on Environmental Quality.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Council on Environmental Quality (CEQ) is proposing this ''Bipartisan Permitting Reform Implementation Rule'' to revise its regulations for implementing the procedural provisions of the National Environmental Policy Act (NEPA), including to implement the Fiscal Responsibility Act's amendments to NEPA. CEQ proposes the revisions to provide for an effective environmental review process that promotes better decision making; ensure full and fair public involvement; provide for an efficient process and regulatory certainty; and provide for sound decision making grounded in science, including consideration of relevant environmental, climate change, and environmental justice effects. CEQ proposes these changes to better align the provisions with CEQ's extensive experience implementing NEPA; CEQ's perspective on how NEPA can best inform agency decision making; longstanding Federal agency experience and practice; NEPA's statutory text and purpose, including making decisions informed by science; and case law interpreting NEPA's requirements. CEQ invites comments on the proposed revisions.

DATES:

Comments: CEQ must receive comments by September 29, 2023.

Public meetings: CEQ will conduct four virtual public meetings for the proposed rule on Saturday, August 26, 2023, from 1 p.m. to 4 p.m. EDT; Wednesday, August 30, 2023, from 5 p.m. to 8 p.m. EDT; Monday, September 11, 2023, from 1 p.m. to 4 p.m. EDT; and Thursday, September 21, 2023, from 2 p.m. to 5 p.m. EDT. For additional information and to register for the meetings, please visit CEQ's website at *www.nepa.gov.*

ADDRESSES: You may submit comments, identified by docket number CEQ–2023–0003, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–456–6546.
- *Mail:* Council on Environmental Quality, 730 Jackson Place NW, Washington, DC 20503.

Instructions: All submissions received must include the agency name, ''Council on Environmental Quality,'' and docket number, CEQ–2023–0003, for this rulemaking. All comments received will be posted without change to *https://www.regulations.gov,* including any personal information provided. Please do not submit electronically any information you consider private, Confidential Business Information (CBI), or other information, the disclosure of which is restricted by statute.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Amy B. Coyle, Deputy General Counsel, 202–395–5750, *Amy.B.Coyle@ceq.eop.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

A. NEPA Statute

Congress enacted NEPA in 1969 by a unanimous vote in the Senate and a nearly unanimous vote in the House to declare an ambitious and visionary national policy to promote environmental protection for present and future generations.[1] President Nixon signed NEPA into law on January 1, 1970. NEPA seeks to ''encourage productive and enjoyable harmony'' between humans and the environment, recognizing the ''profound impact'' of human activity and the ''critical importance of restoring and maintaining environmental quality'' to the overall welfare of humankind. 42 U.S.C. 4321, 4331.

Furthermore, NEPA seeks to promote efforts that will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of people, making it the continuing policy of the Federal Government to use all practicable means and measures to create and maintain conditions under which humans and nature can exist in productive harmony and fulfill the social, economic, and other requirements of present and future generations of Americans. 42 U.S.C. 4331(a). It also recognizes that each person should have the opportunity to enjoy a healthy environment and has a responsibility to contribute to the preservation and enhancement of the environment. 42 U.S.C. 4331(c).

NEPA requires Federal agencies to interpret and administer Federal policies, regulations, and laws in accordance with NEPA's policies and to consider environmental values in their decision making. 42 U.S.C. 4332. To that end, section 102(2)(C) of NEPA requires Federal agencies to prepare ''detailed statements,'' referred to as environmental impact statements (EISs), for ''every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment'' and, in doing so, provide opportunities for public participation to help inform agency decision making. 42 U.S.C. 4332(2)(C). The EIS process embodies the understanding that informed decisions are better decisions and lead to better environmental outcomes when decision makers understand, consider, and publicly disclose environmental effects of their decisions. The EIS process also enriches understanding of the ecological systems and natural resources important to the Nation and helps guide sound decision making, such as decisions on infrastructure and energy development, in line with high-quality information, including the best available science, information and data, as well as the environmental design arts.

In many respects, NEPA was a statute ahead of its time and remains relevant and vital today. It codifies the common-sense idea of ''look before you leap'' to guide agency decision making, particularly in complex and consequential areas, because conducting sound environmental analysis before agencies take actions reduces conflict and waste in the long run by avoiding unnecessary harm and uninformed decisions. *See, e.g.,* 42 U.S.C. 4332. It establishes a framework for agencies to ground decisions in sound science and recognizes that the public may have important ideas and information on how Federal actions can occur in a manner that reduces potential harms and enhances ecological, social, and economic well-being. *See, e.g., id.*

On June 3, 2023, President Biden signed the Fiscal Responsibility Act of 2023 (FRA) into law, which included amendments to NEPA. Specifically, the FRA amended section 102(2)(C) and added sections 102(2)(D) through (F) and sections 106 through 111. The amendments in section 102(2)(C) largely codify longstanding principles that EISs

[1] *See* Linda Luther, Cong. Rsch. Serv., RL33152, The National Environmental Policy Act: Background and Implementation, 4 (2008), *https://crsreports.congress.gov/product/details?prodcode=RL33152.*

should include discussion of reasonably foreseeable environmental effects of the proposed action, reasonably foreseeable adverse environmental effects that cannot be avoided, and a reasonable range of alternatives to the proposed action. Section 102(2)(D) requires Federal agencies to ensure the professional integrity of the discussion and analysis in an environmental document; section 102(2)(E) requires use of reliable data and resources when carrying out NEPA; and section 102(2)(F) requires agencies to study, develop, and describe technically and economically feasible alternatives.

Section 106 adds provisions for determining the appropriate level of NEPA review. It clarifies that an agency is only required to prepare an environmental document when proposing to take an action that would constitute a final agency action and codifies existing regulations and caselaw that an agency is not required to prepare an environmental document when doing so would clearly and fundamentally conflict with the requirements of another law or a proposed action is non-discretionary. Section 106 also largely codifies the current CEQ regulations and longstanding practice with respect to the use of categorical exclusions (CEs), environmental assessments (EAs), and EISs, as modified by the new provision expressly permitting agencies to adopt CEs from other agencies established in section 109 of NEPA.

Section 107 addresses timely and unified Federal reviews, codifying existing practice with a few minor adjustments, including provisions clarifying lead, joint-lead, and cooperating agency designation, generally requiring development of a single environmental document, directing agencies to develop procedures for project sponsors to prepare EAs and EISs, and prescribing page limits and deadlines similar to current requirements. Section 108 codifies time lengths and circumstances for when agencies can rely on programmatic environmental documents without additional review, and section 109 allows a Federal agency to use another agency's CE. Section 111 adds a variety of definitions. This proposed rule would update the regulations to address how agencies should implement NEPA consistent with the amendments made by the FRA.

B. The Council on Environmental Quality

NEPA established the Council on Environmental Quality (CEQ) in the Executive Office of the President. 42 U.S.C. 4342. For more than 50 years, CEQ has advised presidents on national environmental policy, assisted Federal agencies in their implementation of NEPA, and overseen implementation of a variety of other environmental initiatives from the expeditious and thorough environmental review of infrastructure projects [2] to the sustainability of Federal operations.[3]

NEPA charges CEQ with overseeing and guiding NEPA implementation across the Federal Government. In addition to issuing the regulations for implementing NEPA, 40 CFR parts 1500 through 1508 (referred to throughout as ''the CEQ regulations''), CEQ has issued guidance on numerous topics related to NEPA review. In 1981, CEQ issued the ''Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations,'' [4] which CEQ has routinely identified as an invaluable tool for Federal, Tribal, State, and local governments and officials, and members of the public, who have questions about NEPA implementation.

CEQ also has issued guidance on a variety of other topics, from scoping to cooperating agencies to consideration of effects.[5] For example, in 1997, CEQ issued guidance documents on the consideration of environmental justice in the NEPA context [6] under Executive Order (E.O.) 12898, *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,*[7] and on analysis of cumulative effects in NEPA reviews,[8] two documents that agencies continue to use today. From 2010 to the present, CEQ developed additional guidance on CEs, mitigation, programmatic reviews, and consideration of greenhouse gas (GHG) emissions in NEPA.[9] To ensure

[2] *See, e.g.,* E.O. 14008, *Tackling the Climate Crisis at Home and Abroad,* 86 FR 7619 (Feb. 1, 2021); E.O. 13604, *Improving Performance of Federal Permitting and Review of Infrastructure Projects,* 77 FR 18885 (Mar. 28, 2012); E.O. 13274, *Environmental Stewardship and Transportation Infrastructure Project Reviews,* 67 FR 59449 (Sept. 23, 2002); *see also* Modernizing Federal Infrastructure Review and Permitting Regulations, Policies, and Procedures, 78 FR 30733 (May 22, 2013).

[3] *See, e.g.,* E.O. 14057, *Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability,* 86 FR 70935 (Dec. 13, 2021); E.O. 13834, *Efficient Federal Operations,* 83 FR 23771 (May 22, 2018); E.O. 13693, *Planning for Federal Sustainability in the Next Decade,* 80 FR 15869 (Mar. 25, 2015); E.O. 13514, *Federal Leadership in Environmental, Energy, and Economic Performance,* 74 FR 52117 (Oct. 8, 2009); E.O. 13423, *Strengthening Federal Environmental, Energy, and Transportation Management,* 72 FR 3919 (Jan. 26, 2007); E.O. 13101, *Greening the Government Through Waste Prevention, Recycling, and Federal Acquisition,* 63 FR 49643 (Sept. 16, 1998). For Presidential directives pertaining to other environmental initiatives, see E.O. 13432, *Cooperation Among Agencies in Protecting the Environment With Respect to Greenhouse Gas Emissions From Motor Vehicles, Nonroad Vehicles, and Nonroad Engines,* 72 FR 27717 (May 16, 2007) (requiring CEQ and OMB to implement the E.O. and facilitate Federal agency cooperation to reduce greenhouse gas emissions); E.O. 13141, *Environmental Review of Trade Agreements,* 64 FR 63169 (Nov. 18, 1999) (requiring CEQ and the U.S. Trade Representative to implement the E.O., which has the purpose of promoting Trade agreements that contribute to sustainable development); E.O. 13061, *Federal Support of Community Efforts Along American Heritage Rivers,* 62 FR 48445 (Sept. 15, 1997) (charging CEQ with implementing the American Heritage Rivers initiative); E.O. 13547, *Stewardship of the Ocean, Our Coasts, and the Great Lakes,* 75 FR 43023 (Jul. 22, 2010) (directing CEQ to lead the National Ocean Council); E.O. 13112, *Invasive Species,* 64 FR 6183 (Feb. 8, 1999) (requiring the Invasive Species Council to consult with CEQ to develop guidance to Federal agencies under NEPA on prevention and control of invasive species).

[4] CEQ, Forty Most Asked Questions Concerning CEQ's National Environmental Policy Act Regulations, 46 FR 18026 (Mar. 23, 1981) (''Forty Questions''), *https://www.energy.gov/nepa/downloads/forty-most-asked-questions-concerning-ceqs-national-environmental-policy-act.*

[5] *See, e.g.,* CEQ, Memorandum for General Counsels, NEPA Liaisons and Participants in Scoping (Apr. 30, 1981), *https://www.energy.gov/nepa/downloads/scoping-guidance-memorandum-general-counsels-nepa-liaisons-and-participants-scoping;* CEQ, Incorporating Biodiversity Considerations Into Environmental Impact Analysis Under the National Environmental Policy Act (Jan. 1993), *https://ceq.doe.gov/publications/incorporating_biodiversity.html;* CEQ, Council on Environmental Quality Guidance on NEPA Analyses for Transboundary Impacts (July 1, 1997), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/memorandum-transboundary-impacts-070197.pdf;* CEQ, Designation of Non-Federal Agencies to be Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act (July 28, 1999), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/regs/ceqcoop.pdf;* CEQ, Identifying Non-Federal Cooperating Agencies in Implementing the Procedural Requirements of the National Environmental Policy Act (Sept. 25, 2000), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/memo-non-federal-cooperating-agencies-09252000.pdf;* CEQ & DOT Letters on Lead and Cooperating Agency Purpose and Need (May 12, 2003), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/CEQ-DOT_PurposeNeed_May-2013.pdf.*

[6] CEQ, Environmental Justice: Guidance under the National Environmental Policy Act (Dec. 10, 1997) (''Environmental Justice Guidance''), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/regs/ej/justice.pdf.*

[7] E.O. 12898, *Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations,* 59 FR 7629 (Feb. 16, 1994).

[8] CEQ, Considering Cumulative Effects Under the National Environmental Policy Act (Jan. 1997), *https://ceq.doe.gov/publications/cumulative_effects.html; see also* CEQ, Guidance on the Consideration of Past Actions in Cumulative Effects Analysis (June 24, 2005), *https://www.energy.gov/sites/default/files/nepapub/nepa_documents/RedDont/G-CEQ-PastActsCumulEffects.pdf.*

[9] CEQ, Establishing, Applying, and Revising Categorical Exclusions Under the National Environmental Policy Act (Nov. 23, 2010) (''CE Guidance''), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/NEPA_CE_Guidance_Nov232010.pdf;* CEQ, Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use

Continued

coordinated environmental review, CEQ has issued guidance to integrate NEPA reviews with other environmental review requirements such as the National Historic Preservation Act, E.O. 11988, *Floodplain Management,* and E.O. 11990, *Protection of Wetlands.*[10] Finally, CEQ has provided guidance to ensure efficient and effective environmental reviews, particularly for infrastructure projects.[11]

In addition to guidance, CEQ engages frequently with Federal agencies on their implementation of NEPA. First, CEQ is responsible for consulting with all agencies on the development of their NEPA implementing procedures and determining that those procedures conform with NEPA and the CEQ regulations. Through this process, CEQ engages with agencies to understand their specific authorities and programs to ensure agencies integrate consideration of environmental effects into their decision-making processes. Additionally, CEQ provides feedback and recommendations on how agencies may effectively implement NEPA through their procedures.

Second, CEQ consults with agencies on the efficacy and effectiveness of NEPA implementation. Where necessary or appropriate, CEQ engages with agencies on NEPA reviews for specific projects or project types to provide advice and identify any emerging or cross-cutting issues that would benefit from CEQ issuing formal guidance or assisting with coordination. This includes establishing alternative arrangements for compliance with NEPA when agencies encounter emergency situations where they need to act swiftly while also ensuring they meet their NEPA obligations. CEQ also advises on NEPA compliance when agencies are establishing new programs or implementing new statutory authorities. Finally, CEQ helps advance the environmental review process for projects or initiatives deemed important to an administration such as nationally and regionally significant projects, major infrastructure projects, and consideration of climate change-related effects and effects on communities with environmental justice concerns.[12]

Third, CEQ meets regularly with external stakeholders to understand their perspectives on the NEPA process. These meetings can help inform CEQ's development of guidance or other initiatives and engagement with Federal agencies. Finally, CEQ coordinates with other Federal agencies and components of the White House on a wide array of environmental issues and reviews that intersect with the NEPA process, such as Endangered Species Act consultation or effects to Federal lands and waters from federally authorized activities.

In addition to its NEPA responsibilities, CEQ is currently charged with implementing several of the administration's key environmental priorities. On January 27, 2021, the President signed E.O. 14008, *Tackling the Climate Crisis at Home and Abroad,* to establish a government-wide approach to the climate crisis by reducing GHG emissions across the economy; increasing resilience to climate change-related effects; conserving land, water, and biodiversity; transitioning to a clean-energy economy; advancing environmental justice; and investing in disadvantaged communities.[13] CEQ is leading the President's efforts to secure environmental justice consistent with sections 219 through 223 of the E.O.[14] For example, CEQ has developed the Climate and Economic Justice Screening Tool[15] and collaborates with the Office of Management and Budget (OMB) and the National Climate Advisor on implementing the Justice40 initiative, which sets a goal that 40 percent of the overall benefits of certain Federal investments flow to disadvantaged communities.[16]

Section 205 of the E.O. also charged CEQ with developing the Federal Sustainability Plan, a directive that was augmented by E.O. 14057, *Catalyzing Clean Energy Industries and Jobs Through Federal Sustainability,*[17] to achieve a carbon pollution-free electricity sector and clean and zero-emission vehicle fleets. CEQ also is collaborating with the Departments of the Interior, Agriculture, and Commerce on the implementation of the America the Beautiful Initiative.[18] Additionally, E.O. 14008 requires the Chair of CEQ and the Director of OMB to ensure that Federal permitting decisions consider the effects of GHG emissions and climate change.[19]

CEQ is also instrumental to the President's efforts to institute a government-wide approach to advancing environmental justice. On April 21, 2023, the President signed E.O. 14096, *Revitalizing Our Nation's Commitment to Environmental Justice for All,* to further embed environmental justice into the work of Federal agencies and ensure that all people can benefit from the vital safeguards enshrined in the Nation's foundational environmental and civil rights laws.[20]

of Mitigated Findings of No Significant Impact (Jan. 14, 2011), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Mitigation_and_Monitoring_Guidance_14Jan2011.pdf;* CEQ, National Environmental Policy Act Guidance on Consideration of Greenhouse Gas Emissions and Climate Change, 88 FR 1196 (Jan. 9, 2023) (''2023 GHG Guidance''), *https://ceq.doe.gov/guidance/ceq_guidance_nepa-ghg.html.*

[10] CEQ, Implementation of Executive Order 11988 on Floodplain Management and Executive Order 11990 on Protection of Wetlands (Mar. 21, 1978), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Memorandum-Implementation-of-EO-11988-and-EO-11990-032178.pdf;* CEQ & Advisory Council on Historic Preservation, NEPA and NHPA: A Handbook for Integrating NEPA and Section 106 (Mar. 2013), *https://ceq.doe.gov/docs/ceq-publications/NEPA_NHPA_Section_106_Handbook_Mar2013.pdf.*

[11] *See, e.g.,* CEQ, Improving the Process for Preparing Efficient and Timely Environmental Reviews Under the National Environmental Policy Act (Mar. 6, 2012), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Improving_NEPA_Efficiencies_06Mar2012.pdf;* CEQ, Effective Use of Programmatic NEPA Reviews (Dec. 18, 2014) (''Programmatic Guidance''), *https://www.energy.gov/sites/default/files/2016/05/f31/effective_use_of_programmatic_nepa_reviews_18dec2014.pdf;* OMB & CEQ, M–15–20, Guidance Establishing Metrics for the Permitting and Environmental Review of Infrastructure Projects (Sept. 22, 2015), *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2015/m-15-20.pdf;* OMB & CEQ, M–17–14, Guidance to Federal Agencies Regarding the Environmental Review and Authorization Process for Infrastructure Projects (Jan. 13, 2017), *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/memoranda/2017/m-17-14.pdf.*

[12] *See, e.g.,* Memorandum from President Barack Obama to the Heads of Executive Departments and Agencies, *Speeding Infrastructure Development through More Efficient and Effective Permitting and Environmental Review* (Aug. 31, 2011), *https://obamawhitehouse.archives.gov/the-press-office/2011/08/31/presidential-memorandum-speeding-infrastructure-development-through-more;* E.O. 13807, *Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects,* 82 FR 40463 (Aug. 24, 2017).

[13] E.O. 14008, *supra* note 2.

[14] E.O. 14008's direction to advance environmental justice reinforces and reflects longstanding policy established in E.O. 12898 and advances the related though distinct policy defined more broadly in E.O. 13985, *Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,* that the Federal Government ''pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality.'' 86 FR 7009 (Jan. 25, 2021), sec. 1.

[15] CEQ, *Explore the Map,* Climate and Economic Justice Screening Tool, *https://screeningtool.geoplatform.gov/.*

[16] E.O. 14008, *supra* note 2, sec. 223.

[17] E.O. 14057, *supra* note 3.

[18] E.O. 14008, *supra* note 2.

[19] *Id.* at sec. 213(a); *see also id.,* sec. 219 (directing agencies to ''make achieving environmental justice part of their missions by developing programs, policies, and activities to address the disproportionately high and adverse human health, environmental, climate-related and other cumulative impacts on disadvantaged communities'').

[20] E.O. 14096, *Revitalizing Our Nation's Commitment to Environmental Justice for All,* 88 FR 25251 (Apr. 26, 2023). E.O. 14096 builds upon efforts to advance environmental justice and equity

The E.O. charges each agency with making achieving environmental justice part of its mission consistent with statutory authority,[21] and requires each agency to submit to the Chair of CEQ and make publicly available an Environmental Strategic Plan setting forth the agency's goals and plans for advancing environmental justice.[22] Further, section 8 of the E.O. establishes a White House Office of Environmental Justice within CEQ.

Finally, CEQ is staffed with experts with decades of NEPA experience. CEQ's diverse array of responsibilities and expertise has long influenced the implementation of NEPA, and CEQ relied extensively on this experience in developing this rulemaking.

C. NEPA Implementation 1970–2019

Following shortly after the enactment of NEPA, President Nixon issued E.O. 11514, *Protection and Enhancement of Environmental Quality,* directing CEQ to issue guidelines for implementation of section 102(2)(C) of NEPA.[23] In response, CEQ in April 1970 issued interim guidelines, which addressed the provisions of section 102(2)(C) of the Act regarding EIS requirements.[24] CEQ revised the guidelines in 1971 and 1973 to address public involvement and introduce the concepts of EAs and draft and final EISs.[25]

In 1977, President Carter issued E.O. 11991, *Relating to Protection and Enhancement of Environmental Quality,* amending E.O. 11514 and directing CEQ to issue regulations for implementation of section 102(2)(C) of NEPA and requiring that Federal agencies comply with those regulations.[26] CEQ promulgated its NEPA regulations in 1978.[27] Issued 8 years after NEPA's enactment, the NEPA regulations reflected CEQ's interpretation of the statutory text and Congressional intent, expertise developed through issuing and revising the CEQ guidelines and advising Federal agencies on their implementation of NEPA, initial interpretations of the courts, and Federal agency experience implementing NEPA. The 1978 regulations reflected the fundamental principles of informed and science-based decision making, transparency, and public engagement Congress established in NEPA. The regulations further required agency-level implementation, directing Federal agencies to issue and update periodically agency-specific implementing procedures to supplement CEQ's procedures and integrate the NEPA process into the agencies' specific programs and processes. Consistent with 42 U.S.C. 4332(2)(B), the regulations also required agencies to consult with CEQ in the development or update of these agency-specific procedures to ensure consistency with CEQ's regulations.

CEQ made typographical amendments to the 1978 implementing regulations in 1979[28] and amended one provision in 1986 (CEQ refers to these regulations, as amended, as the ''1978 regulations'' in this preamble).[29] Otherwise, CEQ left the regulations unchanged for over 40 years. As a result, CEQ and Federal agencies developed extensive experience implementing the 1978 regulations, and a large body of agency practice and case law developed based on them.

D. 2020 Amendments to the CEQ Regulations

On August 15, 2017, President Trump issued E.O. 13807, *Establishing Discipline and Accountability in the Environmental Review and Permitting Process for Infrastructure Projects,*[30] which directed CEQ to establish and lead an interagency working group to identify and propose changes to the NEPA regulations.[31] In response, CEQ issued an advance notice of proposed rulemaking (ANPRM) on June 20, 2018,[32] and a notice of proposed rulemaking (NPRM) on January 10, 2020, proposing broad revisions to the 1978 regulations.[33] A wide range of stakeholders submitted more than 12,500 comments on the ANPRM[34] and 1.1 million comments on the proposed rule,[35] including from state and local governments, Tribes, environmental advocacy organizations, professional and industry associations, other advocacy or non-profit organizations, businesses, and private citizens. Many commenters provided detailed feedback on the legality, policy wisdom, and potential consequences of the proposed amendments. In keeping with the proposed rule, the final rule, promulgated on July 16, 2020 (''2020 regulations'' or ''2020 rule''), made wholesale revisions to the regulations; it took effect on September 14, 2020.[36]

In the months that followed the issuance of the 2020 regulations, five lawsuits were filed challenging the 2020 rule.[37] These cases challenge the 2020 rule on a variety of grounds, including under the Administrative Procedure Act (APA), NEPA, and the Endangered Species Act, contending that the rule exceeded CEQ's authority and that the related rulemaking process was procedurally and substantively defective. In response to CEQ's motions and joint motions, the district courts issued temporary stays in each of these cases, except for *Wild Virginia* v. *Council on Environmental Quality,* which the district court dismissed without prejudice on June 21, 2021.[38] The Fourth Circuit affirmed that dismissal on December 22, 2022.[39]

consistent with the policy advanced in documents including E.O. 13985, E.O. 14008, and E.O. 12898. *See, e.g.,* note 14, *supra.*

[21] E.O. 14096, *supra* note 20, sec. 3.

[22] *Id.* at sec. 4.

[23] E.O. 11514, *Protection and Enhancement of Environmental Quality,* 35 FR 4247 (Mar. 7, 1970), sec. 3(h).

[24] *See* Statements on Proposed Federal Actions Affecting the Environment, 35 FR 7390 (May 12, 1970) (interim guidelines).

[25] Statements on Proposed Federal Actions Affecting the Environment, 36 FR 7724 (Apr. 23, 1971) (final guidelines); Preparation of Environmental Impact Statements, 38 FR 10856 (May 2, 1973) (proposed revisions to the guidelines); Preparation of Environmental Impact Statements: Guidelines, 38 FR 20550 (Aug. 1, 1973) (revised guidelines).

[26] E.O. 11991, *Relating to Protection and Enhancement of Environmental Quality,* 42 FR 26967 (May 25, 1977).

[27] Implementation of Procedural Provisions, 43 FR 55978 (Nov. 29, 1978).

[28] Implementation of Procedural Provisions; Corrections, 44 FR 873 (Jan. 3, 1979).

[29] National Environmental Policy Act Regulations; Incomplete or Unavailable Information, 51 FR 15618 (Apr. 25, 1986) (amending 40 CFR 1502.22).

[30] E.O. 13807, *supra* note 12.

[31] *Id.,* sec. 5(e)(iii).

[32] Update to the Regulations for Implementing the Procedural Provisions of the National Environmental Policy Act, 83 FR 28591 (June 20, 2018).

[33] Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 FR 1684 (Jan. 10, 2020).

[34] *See* Docket No. CEQ–2018–0001, *https://www.regulations.gov/document/CEQ-2018-0001-0001.*

[35] *See* Docket No. CEQ–2019–0003, *https://www.regulations.gov/document/CEQ-2019-0003-0001.*

[36] Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act, 85 FR 43304 (July 16, 2020) (''2020 Final Rule'').

[37] *Wild Va.* v. *Council on Env't Quality,* No. 3:20cv45 (W.D. Va. 2020); *Env't Justice Health All.* v. *Council on Env't Quality,* No. 1:20cv06143 (S.D.N.Y. 2020); *Alaska Cmty. Action on Toxics* v. *Council on Env't Quality,* No. 3:20cv5199 (N.D. Cal. 2020); *California* v. *Council on Env't Quality,* No. 3:20cv06057 (N.D. Cal. 2020); *Iowa Citizens for Cmty. Improvement* v. *Council on Env't Quality,* No. 1:20cv02715 (D.D.C. 2020). Additionally, in *The Clinch Coalition* v. *U.S. Forest Serv.,* No. 2:21cv00003 (W.D. Va. 2020), plaintiffs challenged the U.S. Forest Service's NEPA implementing procedures, which established new categorical exclusions, and, relatedly, the 2020 rule's provisions on categorical exclusions.

[38] *Wild Va.* v. *Council on Env't Quality,* 544 F. Supp. 3d 620 (W.D. Va. 2021).

[39] *Wild Va.* v. *Council on Env't Quality,* 56 F.4th 281 (4th Cir. 2022).

E. CEQ's Review of the 2020 Regulations

On January 20, 2021, President Biden issued E.O. 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,*[40] to establish an administration policy to listen to the science; improve public health and protect our environment; ensure access to clean air and water; limit exposure to dangerous chemicals and pesticides; hold polluters accountable, including those who disproportionately harm communities of color and low-income communities; reduce GHG emissions; bolster resilience to the impacts of climate change; restore and expand the Nation's treasures and monuments; and prioritize both environmental justice and the creation of well-paying union jobs necessary to achieve these goals.[41] The Executive Order calls for Federal agencies to review existing regulations issued between January 20, 2017, and January 20, 2021, for consistency with the policy it articulates and to take appropriate action.[42] The Executive Order also revokes E.O. 13807 and directs agencies to take steps to rescind any rules or regulations implementing it.[43] An accompanying White House fact sheet, published on January 20, 2021, specifically identified the 2020 regulations for CEQ's review for consistency with E.O. 13990's policy.[44]

Consistent with E.O. 13990 and E.O. 14008, CEQ has reviewed the 2020 regulations and engaged in a multi-phase rulemaking process to ensure that the NEPA implementing regulations provide for sound and efficient environmental review of Federal actions, including those actions integral to tackling the climate crisis, in a manner that enables meaningful public participation, provides for an expeditious process, discloses climate change-related effects, advances environmental justice, respects Tribal sovereignty, protects our Nation's resources, and promotes better and more equitable environmental and community outcomes.

First, CEQ issued an interim final rule on June 29, 2021, amending the requirement in 40 CFR 1507.3(b) for agencies to propose changes to existing agency-specific NEPA procedures by September 14, 2021, to make those procedures consistent with the 2020 regulations.[45] CEQ extended the date by 2 years to avoid agencies proposing changes to agency-specific implementing procedures on a tight deadline to conform to regulations that are undergoing extensive review and would likely change in the near future.

Next, on October 7, 2021, CEQ issued a ''Phase 1'' proposed rule to focus on a discrete set of provisions designed to restore three elements of the 1978 regulations.[46] CEQ proposed changes to the provisions it considered most critical to address, revise, and clarify while completing the comprehensive review. First, CEQ proposed to revise 40 CFR 1502.13 to clarify that agencies have discretion to consider a variety of factors when assessing an application for authorization by removing a requirement that an agency base the purpose and need on the goals of an applicant and the agency's statutory authority. CEQ also proposed a conforming edit to the definition of ''reasonable alternatives'' in 40 CFR 1508.1(z). Second, CEQ proposed to remove language in 40 CFR 1507.3 that could be construed to limit agencies' flexibility to develop or revise procedures to implement NEPA specific to their programs and functions that may go beyond CEQ's regulatory requirements. Finally, CEQ proposed to revise the definition of ''effects'' in 40 CFR 1508.1(g) to restore the substance of the definitions of ''effects'' and ''cumulative impacts'' contained in the 1978 regulations. CEQ received 94,458 written comments in response to the proposed rule. CEQ issued a Phase 1 final rule on April 20, 2022,[47] which finalized the proposed revisions.

CEQ received a variety of comments on the Phase 1 proposed rule suggesting additional provisions or changes that CEQ should consider as part of the Phase 2 rulemaking.[48] For example, commenters requested that CEQ strengthen public participation requirements and encourage more robust public engagement; better incorporate environmental justice and climate change considerations into the regulations; further address the climate and biodiversity crises; modernize environmental review of renewable energy projects; and further refine definitions, including human environment, major Federal action, and effects. In addition, commenters suggested that CEQ address page and time limits; mitigation; tiering; CEs; and improved coordination among Federal, Tribal, State, and local agencies and governments. Additionally, many of the comments on the Phase 1 proposed rule's changes to 40 CFR 1502.13 on purpose and need also included suggestions for changes to 40 CFR 1502.14 and the discussion of alternatives. Where appropriate, CEQ summarizes these Phase 1 comments as they relate to specific subsections of Section II of the preamble.

Here, in this Phase 2 notice of proposed rulemaking (NPRM), CEQ initiates a broader rulemaking to revise, update, and modernize the NEPA implementing regulations. Informed by CEQ's extensive experience implementing NEPA, CEQ proposes further revisions to ensure the NEPA process provides for efficient and effective environmental reviews that are guided by science and are consistent with the statute's text and purpose; enhance clarity and certainty for Federal agencies, project proponents, and the public; inform the public about the potential environmental effects of Federal Government actions and enable full and fair public participation; and ultimately promote better informed Federal decisions that protect and enhance the quality of the human environment, including by ensuring climate change, environmental justice, and other environmental issues are fully accounted for in agencies' decision-making processes.

As part of CEQ's review, CEQ engaged in extensive outreach with a wide variety of interested and experienced parties to solicit their feedback and recommendations on what new elements CEQ should consider adding; what elements from the 1978 regulations CEQ should consider restoring; what existing elements of the NEPA regulations CEQ should consider clarifying, revising, or removing; and what existing elements CEQ should retain in their current form. CEQ convened a Federal interagency working group made up of NEPA practitioners, attorneys, and other experts to hear and discuss their recommendations on a wide variety of issues in the NEPA regulations and more generally with the environmental review process. The Federal agency participants represented the broad array of NEPA practice and environmental expertise across the

[40] 86 FR 7037 (Jan. 25, 2021).

[41] *Id.* at sec. 1.

[42] *Id.*

[43] *Id.* at sec. 7.

[44] The White House, Fact Sheet: List of Agency Actions for Review (Jan. 20, 2021), *https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/.*

[45] Deadline for Agencies to Propose Updates to National Environmental Policy Act Procedures, 86 FR 34154 (June 29, 2021).

[46] National Environmental Policy Act Implementing Regulations Provisions, 86 FR 55757 (Oct. 7, 2021).

[47] National Environmental Policy Act Implementing Regulations Revisions, 87 FR 23453 (Apr. 20, 2022) (''Phase 1 Final Rule'').

[48] *See* CEQ, National Environmental Policy Act Implementing Regulations Revision Phase 1 Response to Comments (Apr. 2022) (''Phase 1 Response to Comments''), *https://www.regulations.gov/document/CEQ-2021-0002-39427.*

Federal Government, including land management, infrastructure, resource conservation, climate, and environmental justice experts.

CEQ also hosted or participated in over 60 meetings with external parties, such as environmental organizations, business and industry organizations (including timber, energy, air, grazing, mining, and transportation organizations), Tribal Nations, State governments, environmental justice organizations, academics, and labor organizations. Additionally, CEQ held a Tribal consultation specifically on the Phase 2 regulations and the updates to CEQ's GHG guidance on November 12, 2021. CEQ considered the feedback received during these engagements in the development of this proposed rule and has included summaries of the external engagements in the docket.

Finally, as discussed in Section I.B, CEQ relies on its extensive experience overseeing and implementing NEPA in the development of this rule. CEQ has over 50 years of experience advising Federal agencies on the implementation of NEPA. CEQ collaborates daily with Federal agencies on specific NEPA reviews, provides government-wide guidance on NEPA implementation, consults with agencies on the development of agency-specific NEPA implementing procedures and determines they conform with NEPA and the CEQ regulations, and advises the President on a vast array of environmental issues. This experience also enables CEQ to clarify the patchwork of fact-specific judicial decisions that have evolved under NEPA. This rulemaking seeks to bring clarity and predictability to Federal agencies and outside parties whose activities require Federal action and therefore trigger NEPA review, while also facilitating better environmental and social outcomes due to informed decision making.

II. Summary of Proposed Rule

This section summarizes CEQ's proposed revisions to its NEPA implementing regulations and the rationale for the changes. CEQ's proposed changes fall into five general categories. First, CEQ proposes revisions to implement the amendments to NEPA made by the FRA. Second, where CEQ determined it made sense to do so, CEQ proposes to amend provisions, which the 2020 regulations revised, to revert to the language from the 1978 regulations that was in effect for more than 40 years, subject to minor revisions for clarity. Third, CEQ proposes to remove certain provisions added by the 2020 rule that CEQ considers imprudent or legally unsettled. Fourth, CEQ proposes to amend certain provisions to enhance consistency and provide clarity to improve the efficiency and effectiveness of the environmental review process. Fifth, CEQ proposes revisions to the regulations to implement decades of CEQ and agency experience implementing and complying with NEPA, foster science-based decision making—including decisions that account for climate change and environmental justice—improve the efficiency and effectiveness of the environmental review process, and better effectuate NEPA's statutory purposes. CEQ is retaining many of the changes made in the 2020 rulemaking particularly where those changes codified longstanding practice or guidance or enhanced the efficiency and effectiveness of the NEPA process.

In response to the Phase 1 proposed rule, CEQ received many comments on provisions not addressed in Phase 1. CEQ indicated in the Phase 1 final rule that it would consider such comments during the development of this Phase 2 rulemaking. CEQ has done so, and where applicable, this NPRM provides a high-level summary of the important issues raised in those public comments.

While some comments have advocated for a straight return to the 1978 regulations, CEQ does not consider this to be the appropriate approach. As part of its review, CEQ evaluated the provisions of the 2020 regulations and sought feedback from NEPA experts and interested stakeholders to identify provisions that, as written, add value to the NEPA process or that require amendments to enhance clarity or improve efficiency and effectiveness. For example, CEQ identified for retention the inclusion of Tribal interests throughout the regulations, the integration of mechanisms to facilitate better interagency cooperation, and the reorganization and modernization of provisions addressing certain elements of the process to make the regulations easier to understand and follow. CEQ considers it important that the regulations meet current goals and objectives, including to promote the development of NEPA documents that are concise but also include the information needed to inform decision makers and reflect public input. CEQ's proposed revisions to the regulations emphasize the importance of transparency and public engagement, reflecting modern practices and changing needs, while also recognizing the discretion and flexibility that Federal agencies need to respond and move efficiently and effectively through the NEPA process.

A. Proposed Changes Throughout Parts 1500–1508 [49]

CEQ proposes several revisions throughout parts 1500–1508 to provide consistency, improve clarity, and correct grammatical errors. Improved clarity reduces confusion and results in more consistent implementation, thereby improving the efficiency of the NEPA process and reducing the risk of litigation.

For greater consistency and clarity, CEQ proposes to change the word ''impact'' to ''effect'' where this term is used as a noun because these two words are synonymous. Throughout the regulations, to improve clarity, CEQ proposes to use the word ''significant'' only to modify the term ''effects.'' Accordingly, throughout the regulations, where ''significant'' modifies a word other than ''effects,'' CEQ proposes to replace ''significant'' with another accurate adjective, typically ''important'' or ''substantial,'' which have been used throughout the CEQ regulations since 1978. In doing so, CEQ seeks to avoid confusion about what ''significant'' means in these other contexts by limiting its use to describing ''significant effects.'' The one exception to this change would be that CEQ proposes for the regulations to continue to refer to a finding of no significant impact (FONSI), which CEQ would leave intact because the concept of a FONSI is entrenched in practice and case law. CEQ heard from public comments and agency feedback on the Phase 1 rulemaking that use of the word ''significant'' in phrases such as ''significant issues'' or ''significant actions'' creates confusion on what the word ''significant'' means.[50] The proposed change also aligns with the proposed definition of ''significant effects'' in § 1508.1(jj),[51] as discussed in section II.J.13. CEQ does not intend these proposed changes to substantively change the meaning of the provisions.

For clarity, CEQ proposes to change ''statement'' to ''environmental impact statement'' and ''assessment'' to ''environmental assessment'' where the regulations only use the short form in the paragraph. See, *e.g.,* §§ 1502.3 and 1506.3(e)(1) through (e)(3).

[49] CEQ prepared a redline of this proposed rule's changes to the current CEQ regulations and provided it in the docket as a tool to facilitate public review of this NPRM.

[50] Phase 1 Response to Comments, *supra* note 48, at 120–21.

[51] In the preamble, CEQ uses the section symbol (§) to refer to the proposed regulations as set forth in this NPRM and 40 CFR to refer to the current CEQ regulations as set forth in 40 CFR parts 1500–1508. When referencing specific regulatory sections in place prior to the 2020 final rule, CEQ uses 40 CFR but adds ''(2019).''

CEQ also proposes to make grammatical corrections or other edits throughout the regulations where CEQ considers the changes necessary for the reader to understand fully the meaning of the sentences. Finally, CEQ proposes to update the authorities for each part, update the references to NEPA as amended by the FRA, and fix internal cross references to other sections of the regulations throughout to follow the correct **Federal Register** format.

B. Proposed Revisions To Update Part 1500, Purpose and Policy

1. Purpose (§ 1500.1) and Policy (§ 1500.2)

Consistent with the approach taken in the 1978 regulations, CEQ proposes to address the purpose of the CEQ regulations in § 1500.1, ''Purpose,'' and reinstate § 1500.2, ''Policy.'' In § 1500.1, CEQ proposes to restore much of the language from the 1978 regulations and further incorporate the policies Congress established in the NEPA statute. CEQ is proposing these changes to restore text regarding NEPA's purpose and goals, placing the regulations into their broader context. CEQ also finds value in restating the policies of the Act within the regulations, which would improve readability by avoiding the need for cross references to material outside the four corners of the regulations.

Specifically, CEQ proposes to revise 40 CFR 1500.1(a) by subdividing it into § 1500.1(a), (a)(1), and (a)(2), and restoring language from the 1978 regulations that states the principles and policies Congress established in sections 101 and 102 of NEPA. CEQ is proposing to remove the language that describes NEPA as a purely procedural statute because, while correct, CEQ considers that language to be an inappropriately narrow view of NEPA's purpose that minimizes some of the broader goals of NEPA described in section I.A. While CEQ agrees that a NEPA analysis does not dictate a particular outcome by the decision maker, Congress established the NEPA process to provide for better informed Federal decision making and improve environmental outcomes, and those goals are not fulfilled if the NEPA analysis is treated merely as a check-the-box exercise. In short, CEQ does not consider it necessary to repeatedly emphasize the procedural nature of NEPA, which may suggest that NEPA mandates a rote paperwork exercise and de-emphasizes the Act's larger goals and purposes. Instead, CEQ remains cognizant of the goals Congress intended to achieve through the NEPA process in developing its implementing regulations, and agencies should carry out NEPA's procedural requirements in a manner faithful to the purposes of the statute.

In § 1500.1(a)(1), CEQ proposes to retain the sentence summarizing section 101(a) of NEPA and add a second sentence summarizing section 101(b) to clarify that agencies also should accomplish the purposes described in section 101(b) through NEPA reviews. Including this language in § 1500.1(a)(1) would help agencies understand what the regulations refer to when the regulations direct or encourage agencies to act in a manner consistent with the purposes or policies of the Act. *See, e.g.,* §§ 1500.2(a), 1500.6, 1501.1(a), 1502.1(a), and 1507.3(b).

In § 1500.1(a)(2), CEQ proposes to restore generally the language of the 1978 regulations stating that the purpose of the regulations is to convey what agencies should and must do to comply with NEPA to achieve its purpose. CEQ proposes to strike the language added by the 2020 rule that NEPA requires Federal agencies to provide a detailed statement for major Federal actions, that the purpose and function of NEPA is satisfied if agencies have considered environmental information and informed the public, and that NEPA does not mandate particular results. While it is true that NEPA does not mandate particular results in specific decision-making processes, this language unduly minimizes Congress's understanding that procedures ensuring that agencies analyze, consider, and disclose environmental effects will lead to better substantive outcomes, and is inconsistent with Congress's statements of policy in the NEPA statute.

In § 1500.1(b), CEQ proposes to strike the first two sentences added by the 2020 rule and restore language from the 1978 regulations emphasizing the importance of the early identification of high-quality information that is relevant to a decision. Early identification and consideration of issues using high-quality information have long been fundamental to the NEPA process, particularly because this facilitates comprehensive analysis of alternatives and timely and efficient decision making, and CEQ considers it important to emphasize these considerations in this section. The proposed changes also emphasize that the environmental information that agencies use in the NEPA process should be high-quality, science-based, and accessible. CEQ proposes to strike the first two sentences of this paragraph, which the 2020 rule added, because they also provide an unnecessarily narrow view of the purposes of NEPA and its implementing regulations.

Finally, CEQ proposes in a new § 1500.1(c) to restore text from the 1978 regulations, most of which the 2020 rule deleted, emphasizing the importance of NEPA reviews for informed decision making. The proposed changes to § 1500.1 recognize that the procedural provisions of NEPA are intended to further the purpose and goals of the Act. One of those goals is to make improved and sound government decisions.

The 2020 rule struck 40 CFR 1500.2 (2019) and integrated policy language into 40 CFR 1500.1 (2020).[52] CEQ is proposing to once again provide for two sections, renaming § 1500.1 to ''Purpose'' and restoring § 1500.2 as ''Policy.'' CEQ is proposing to restore with some updates the language of the 1978 regulations to § 1500.2.

In § 1500.2(a), CEQ proposes to restore the 1978 language directing agencies to interpret their authorities consistent with the policies of NEPA and the CEQ regulations to the fullest extent possible. Paragraph (b) would restore with clarifying edits the 1978 language directing agencies to implement procedures that facilitate a meaningful NEPA process to the fullest extent possible and emphasize that environmental documents should be concise and clear. Paragraph (c) would direct agencies to integrate NEPA with other planning and environmental review requirements to the fullest extent possible, which promotes efficient processes. CEQ proposes to modernize language from the 1978 regulations in paragraph (d) to emphasize public engagement, including with communities with environmental justice concerns, which often include communities of color, low-income communities, and indigenous communities, and Tribal communities. CEQ views an emphasis on engagement with such communities to be important because agencies have not always meaningfully engaged with them and such communities have been disproportionately and adversely affected by certain Federal activities.

In proposing to make this change to emphasize public engagement, CEQ notes that the obligation to consult with Tribal Nations on a nation-to-nation basis is distinct from the public engagement requirements of NEPA.[53] CEQ invites comment on whether

[52] 2020 Final Rule, *supra* note 36, at 43316–17.

[53] *See* E.O. 13175, *Consultation and Coordination with Indian Tribal Governments,* 65 FR 67249 (Nov. 9, 2000); Presidential Memorandum, Tribal Consultation and Strengthening Nation-to-Nation Relationships, 86 FR 7491 (Jan. 29, 2021), *https://www.federalregister.gov/d/2021-02075.*

additional changes to the NEPA regulations would be appropriate in light of the obligation for Tribal consultation.

In paragraph (e), CEQ proposes to restore language from the 1978 regulations regarding the identification of alternatives that avoid or minimize adverse effects. CEQ is proposing to add examples of such alternatives, including those that will reduce climate change-related effects or address effects that disproportionately affect communities with environmental justice concerns consistent with E.O. 12898 and E.O. 14096, to highlight the importance of considering such effects in environmental documents, consistent with NEPA's requirements, including the consideration of high-quality information, such as best available science and data.[54]

Finally, in paragraph (f), CEQ proposes to restore the direction from the 1978 regulations to use all practicable means to restore and enhance the environment, consistent with the policies of NEPA. These proposed restorations and additions to § 1500.2(d), (e), and (f) reflect longstanding practice among Federal agencies and align with NEPA's statutory policies, including to avoid environmental degradation, preserve historic, cultural, and natural resources, and ''attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.'' 42 U.S.C. 4331(b).

The 2020 rule removed the Policy section stating that it was duplicative of other sections.[55] However, CEQ proposes to restore and update this section because a robust articulation of the Act's policy principles is fundamental to the NEPA process. CEQ also considers it helpful to agency practitioners and the public to have a consolidated listing of policy objectives regardless of whether other sections of the regulations address those objectives.

2. NEPA Compliance (§ 1500.3)

CEQ proposes to remove from § 1500.3 provisions added by the 2020 rule regarding exhaustion and remedies, restore some language from the 1978 regulations removed by the 2020 rule, and make other conforming edits. Specifically, in § 1500.3(a), CEQ proposes to remove the phrase ''except where compliance would be inconsistent with other statutory requirements'' because this is addressed by § 1500.6. CEQ also proposes to remove the reference to E.O. 13807, which E.O. 13990 revoked, as well as the reference to section 309 of the Clean Air Act because this provision is implemented by EPA.

CEQ proposes to delete 40 CFR 1500.3(b), including its paragraphs. The process established by the 2020 rule provides that first, an agency must request in its notice of intent (NOI) comments on all relevant information, studies, and analyses on potential alternatives and effects. 40 CFR 1500.3(b)(1). Second, the agency must summarize all the information it receives in the draft EIS and specifically seek comment on it. 40 CFR 1500.3(b)(2), 1502.17, 1503.1(a)(3). Third, decision makers must certify in the record of decision (ROD) that they considered all the alternatives, information, and analyses submitted by public commenters. 40 CFR 1500.3(b)(4), 1505.2(b). Fourth, any comments not submitted within the comment period are considered forfeited as unexhausted. 40 CFR 1500.3(b)(3), 1505.2(b). By adding this exhaustion process, the 2020 rule aimed to limit legal challenges and judicial remedies.[56]

CEQ proposes to remove this process because it establishes an inappropriately stringent exhaustion requirement for public commenters and agencies. It is unsettled whether CEQ has the authority under NEPA to set out an exhaustion requirement that bars parties from bringing claims on the grounds that an agency's compliance with NEPA violated the APA, pursuant to 5 U.S.C. 702. While the 2020 rule correctly identifies instances in which courts have ruled that parties may not raise legal claims based on issues that they themselves did not raise during the comment period,[57] other courts have sometimes ruled that a plaintiff can bring claims where another party raised an issue in comments or where the agency should have identified an issue on its own. *Pac. Coast Fed'n of Fishermen's Ass'ns* v. *U.S. Dep't of Interior,* 929 F. Supp. 2d 1039, 1045–46 (E.D. Cal. 2013); *Wyo. Lodging and Rest. Ass'n* v. *U.S. Dep't of Interior,* 398 F. Supp. 2d 1197, 1210 (D. Wyo. 2005); *see Pub. Citizen,* 541 U.S. at 765 (noting that ''[T]he agency bears the primary responsibility to ensure that it complies with NEPA . . . and an EA's or an EIS' flaws might be so obvious that there is no need for a commentator to point them out specifically in order to preserve its ability to challenge a proposed action''). Because the fundamental question raised by these cases is the availability of a cause of action under the APA, and not a question of interpreting NEPA, CEQ considers this question more appropriate for the courts to determine. Further, nothing in this revision would limit the positions the Federal Government may take regarding whether, based on the facts of a particular case, a particular issue has been forfeited by a party's failure to raise it before the agency, and removing this provision does not suggest that a party should not be held to have forfeited an issue by failing to raise it. By deleting the exhaustion requirements, CEQ does not take the position that plaintiffs may raise new and previously unraised issues in litigation. Rather, CEQ considers this to be a question of general administrative law and therefore the courts to be the proper venue to determine whether any particular claim can proceed.

Moreover, the exhaustion requirement established in the 2020 rule is at odds with longstanding agency practice. While courts have ruled that agencies are not required to do so, *see, e.g., Pub. Citizen,* 541 U.S. at 764–65 (finding that where a party does not raise an objection in their comments on an EA, the party forfeits any objection to the EA on that ground), agencies have discretion to consider and respond to comments submitted after a comment period ends. The exhaustion requirement established in the 2020 regulations could encourage agencies to disregard important information presented to the agency shortly after a comment period closes, and such a formalistic approach would not advance NEPA's goal of informed decision making.

To be clear, this change does not relieve parties interested in participating in, commenting on, or ultimately challenging a NEPA analysis

[54] Consideration of environmental justice and climate change-related effects has long been part of NEPA analysis. *See, e.g.,* Environmental Justice Guidance, *supra* note 6, and *Ctr. For Biological Diversity* v. *Nat'l Highway Traffic Safety Admin.,* 538 F.3d 1172 (9th Cir. 2008). *See also* 42 U.S.C. 4331(b) (''[I]t is the continuing responsibility of the Federal Government to . . . assure for *all* Americans safe, healthful, productive, and esthetically and culturally pleasing surroundings . . . [and to] maintain, wherever possible, an environment which supports diversity and variety of individual choice'' (emphasis added); 42 U.S.C. 4332(2)(F) (''all agencies of the Federal Government shall . . . recognize the worldwide and long-range character of environmental problems'').

[55] 2020 Final Rule, *supra* note 36 at 43317.

[56] 2020 Final Rule, *supra* note 36, at 43317–18.

[57] *Id.* (citing *Dep't of Transp.* v. *Pub. Citizen,* 541 U.S. 752 (2004); *Karst Env't. Educ. & Prot., Inc.* v. *Fed. Highway Admin.,* 559 F. App'x 421 (6th Cir. 2014); *Friends of the Norbeck* v. *U.S. Forest Serv.,* 661 F.3d 969 (8th Cir. 2011); *Exxon Mobil Corp.* v. *U.S. EPA,* 217 F.3d 1246 (9th Cir. 2000); *Nat'l Ass'n of Mfrs.* v. *U.S. Dep't of the Interior,* 134 F.3d 1095 (D.C. Cir. 1998)).

of the obligation to ''structure their participation so that it is meaningful.'' *Vt. Yankee Nuclear Power Corp.* v. *Nat. Res. Def. Council, Inc.,* 435 U.S. 519, 553 (1978). As CEQ's regulations have made clear since 1978, parties must provide comments that are as specific as possible to enable agencies to consider and address information during the decision-making processes. *See* 40 CFR 1503.3(a). While commenters should follow the appropriate procedures and time limits, the revisions would provide agencies flexibility to address unusual circumstances.

CEQ proposes to redesignate 40 CFR 1500.3(c), ''Review of NEPA compliance,'' as paragraph (b) and move to paragraph (b) the sentence from 40 CFR 1500.3(d) regarding harmless error for minor, non-substantive errors, which is a concept that has been in place since the 1978 regulations. CEQ proposes to delete the remaining text of 40 CFR 1500.3(c), removing language that noncompliance with NEPA and the CEQ regulations should be resolved as expeditiously as possible. While CEQ agrees with expeditious resolution of issues, CEQ considers this inappropriate for regulatory text as these regulations cannot compel members of the public or courts to resolve NEPA disputes. Rather, the regulations promote public engagement, appropriate analysis, and informed decision making to facilitate NEPA compliance and avoid such disputes from the outset. CEQ also proposes to strike the last sentence in this paragraph regarding bonding and other security requirements, which relates to litigation over an agency action and not the NEPA process itself. It is unsettled whether NEPA provides agencies with authority to promulgate procedures that require plaintiffs to post bonds in litigation brought under the APA. In any case, CEQ does not consider it appropriate to address this issue in the NEPA implementing regulations.

With the exception of the last sentence in 40 CFR 1500.3(d) regarding remedies, which CEQ proposes to move, as discussed earlier in this section, CEQ proposes to delete the remainder of the paragraph. It is questionable whether CEQ has the authority to direct courts about what remedies are available in litigation brought under the APA to challenge NEPA compliance and, in any case, CEQ considers the 2020 rule's addition of this paragraph to be inappropriate. CEQ considers courts to be in the best position to determine the appropriate remedies when a plaintiff successfully challenges an agency's NEPA compliance.

Finally, CEQ proposes to redesignate 40 CFR 1500.3(e), ''Severability,'' as paragraph (c), without change. CEQ intends these regulations to be severable. The proposed rule would amend existing regulations and the NEPA regulations could be functionally implemented if each revision proposed in this rule occurred on its own or in combination with any other subset of proposed revisions. As a result, if a court were to invalidate any particular provision of this rule, allowing the remainder of the rule to remain in effect would still result in a functional NEPA review process. This approach to severability is the same as the approach that CEQ took when it promulgated the 2020 regulations, because those amendments similarly could be layered onto the 1978 regulations individually without disrupting the overarching NEPA review process.

3. Concise and Informative Environmental Documents (§ 1500.4)

CEQ proposes to revise § 1500.4 to emphasize the important values served by concise and informative NEPA documents beyond merely reducing paperwork, such as promoting informed and efficient decision making and facilitating meaningful public participation. Section 1500.4 lists examples of provisions in the CEQ regulations that provide mechanisms by which agencies may prepare concise and informative environmental documents. Each paragraph listed in § 1500.4 includes cross references to regulatory provisions that further the goal of preparing concise and informative documents.

To that end, CEQ proposes to retitle § 1500.4 from ''Reducing paperwork'' to ''Concise and informative environmental documents'' and revise the introductory text to clarify that the paragraphs in this section provide examples of the mechanisms in the regulations that agencies can use to prepare concise and informative environmental documents. CEQ proposes to remove paragraphs (a) and (b) from 40 CFR 1500.4 because they are redundant with § 1500.5(a) and (b) and are more appropriately addressed in the section on reducing delay, as well as paragraph (d) because it is addressed in the revised introductory text. CEQ proposes to redesignate 40 CFR 1500.4(c) and (e) through (q) as § 1500.4 (a) and (b) through (n), respectively.

CEQ proposes to add ''*e.g.,*'' to the cross references listed in § 1500.4(b), (c), and (e) to clarify that they are non-exclusive examples of how agencies can briefly discuss unimportant issues, write in plain language, and reduce emphasis on background material. CEQ would update the cross references to other sections of the subchapter to reflect proposed changes elsewhere in the regulations. In paragraphs (c) and (e), CEQ proposes to expand the reference from EISs to all environmental documents, as the concepts discussed are more broadly applicable. Additionally, in paragraph (e), CEQ proposes to insert ''most'' before ''useful'' to clarify that the environmental documents should not contain portions that are useless.

In § 1500.4(f), CEQ proposes to replace ''significant'' with ''important'' and insert ''unimportant'' to modify ''issues'' consistent with our proposal to only use ''significant'' to modify ''effects.'' CEQ also proposes to clarify in paragraph (f) that scoping may apply to EAs. Finally, CEQ proposes to expand paragraph (h), regarding programmatic review and tiering, to include EAs to align with the proposed changes to § 1501.11. Finally, in paragraph (m), CEQ proposes to insert ''Federal'' before ''agency'' consistent with § 1506.3, which allows adoption of NEPA documents prepared by other Federal agencies.

Concise and informational documents make the NEPA process more accessible and transparent to the public, allowing the public an opportunity to contribute to the NEPA process. The changes proposed in § 1500.4 align the regulations with the intent of NEPA to allow the public to provide input, as well as CEQ's stated goal of increasing transparency, while providing agencies flexibility on how to achieve concise and informative documents. These proposed changes aim to encourage the preparation of documents that can be easily read and understood, which in turn promote informed and efficient decision making.

4. Efficient Process (§ 1500.5)

CEQ proposes minor changes to § 1500.5 to provide clarity and flexibility regarding mechanisms by which agencies can apply the CEQ regulations to improve efficiency in the environmental review process. CEQ proposes these changes to acknowledge that unanticipated events and circumstances beyond agency control may delay the environmental review process, and to recognize that, while these approaches may improve efficiency for many NEPA reviews, they could be inefficient for others. To that end, CEQ proposes to retitle § 1500.5 from ''Reducing delay'' to ''Efficient process'' and revise the introductory text to reflect the new title. The other proposed changes include adding EAs

to paragraph (a) to make the provision consistent with the definition of ''categorical exclusion;'' changing ''real issues'' to ''important issues that required detailed analysis'' in paragraph (f) for consistency with § 1502.4; and expanding the scope of paragraph (h) from EISs to environmental documents to make clear that, regardless of the level of NEPA review, agencies should prepare environmental documents early in the process. Proposed § 1500.5 recognizes the importance of timely information for decision making and encourages agencies to implement the 12 listed mechanisms to achieve timely and efficient NEPA processes.

5. Agency Authority (§ 1500.6)

In § 1500.6, CEQ proposes to revise the second sentence to remove the qualification added in the 2020 rule that agencies must ensure full compliance with the Act ''as interpreted by'' these regulations and instead state that agencies must review and revise their procedures to ensure compliance with NEPA and the CEQ regulations. The phrase added in 2020 could be read to indicate that agencies have no freestanding requirement to comply with NEPA itself, which would be untrue. CEQ also considers the proposed change necessary for consistency with § 1507.3(b), which CEQ revised in the Phase 1 rulemaking to make clear that, while agency procedures must be consistent with the CEQ regulations, agencies have discretion and flexibility to develop procedures beyond the CEQ regulatory requirements, enabling agencies to address their specific programs, statutory mandates, and the contexts in which they operate. CEQ proposes to make conforming edits in §§ 1502.2(d) and 1502.9(b) to remove this phrase.

In the third sentence, CEQ proposes to remove the cross-reference to § 1501.1 for consistency with the proposed modifications to § 1501.1 and restore the intent of language from the 1978 regulations, with modification, explaining that the phrase ''to the fullest extent possible'' means that each agency must comply with section 102 of NEPA unless an agency activity, decision, or action is exempted by law or compliance with NEPA is impossible. Finally, CEQ proposes to strike the last sentence stating that the CEQ regulations do not limit an agency's other authorities or legal responsibilities, which the 2020 rule added to acknowledge the possibility of different statutory authorities with different requirements. While the 2020 regulations contended that this sentence was added for consistency with E.O. 11514, as amended by section 2(g) of E.O. 11991, CEQ considers the sentence superfluous and unnecessarily vague. As stated in the new proposed text, agencies must comply with NEPA in carrying out an activity, decision, or action unless exempted by law or compliance with NEPA is impossible. That description would reflect accurately the directive that Federal agencies comply with the CEQ regulations ''except where such compliance would be inconsistent with statutory requirements.'' [58]

CEQ's proposed revisions to § 1500.6 would clarify that agencies have an independent responsibility to ensure compliance with NEPA and a duty to harmonize NEPA with their other statutory requirements and authorities to the maximum extent possible. This is true as a general matter of statutory construction as well as under the specific statutory mandate of section 102 of NEPA, which requires that ''the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in this [Act].'' 42 U.S.C. 4332(1).

Therefore, compliance with NEPA is only impossible within the meaning of this subsection when the conflict between another statute and the requirements of NEPA are clear, unavoidable, and irreconcilable. Absent exemption by Congress or a court, an irreconcilable conflict exists only if the agency's authorizing statute grants it no discretion to comply with NEPA while also satisfying the statutory mandate.

C. Proposed Revisions To Update Part 1501, NEPA and Agency Planning

CEQ is proposing substantive revisions to all sections in part 1501 except § 1501.2, ''Apply NEPA early in the process,'' to which CEQ proposes minor edits for readability that CEQ considers clarifying and non-substantive. CEQ invites comment on whether it should make any substantive changes to that section or other changes to part 1501.

1. Purpose (§ 1501.1)

CEQ proposes to revert and retitle § 1501.1 to ''Purpose,'' to emphasize the goals of part 1501 consistent with the approach in the 1978 regulations. As discussed further below, CEQ proposes to move some of the NEPA thresholds language in 40 CFR 1501.1 to § 1503.1(a), strike the remaining text, and replace it with new provisions similar to those in the 1978 regulations.

In § 1501.1(a), CEQ proposes to highlight the importance of integrating NEPA early in agency planning processes by generally restoring the language from the 1978 regulations, while also emphasizing that this promotes an efficient process and reduces delay. Restoring this language is consistent with section 102(2)(C) of NEPA and the objective to build into agency decision making, beginning at the earliest point, an appropriate consideration of the environmental aspects of a proposed action. 42 U.S.C. 4332(2)(C). CEQ proposes in paragraph (b) to emphasize early engagement in the environmental review process consistent with other changes proposed throughout the regulations to elevate the importance of early coordination and engagement throughout the NEPA process to identify and address potential issues early in a decision-making process, thereby helping to reduce the overall time required to approve a project and improving outcomes. In new paragraph (c), CEQ proposes to restore text from the 1978 regulations regarding expeditious resolution of interagency disputes as promoted in §§ 1501.7 and 1501.8. Paragraph (d) also would restore the direction to identify the scope of the proposed action and important environmental issues consistent with § 1501.3, thereby enhancing efficiency. Finally, paragraph (e) would highlight the importance of schedules consistent with § 1501.10, which includes provisions requiring agencies to develop a schedule for all environmental reviews and authorizations, as well as §§ 1501.7 and 1501.8, which promote interagency coordination including with respect to schedules.

As discussed further in section II.C.2, CEQ proposes to combine the threshold considerations provision with the process to determine the appropriate level of NEPA review in § 1501.3 by moving 40 CFR 1501.1(a)(1), (2), (4), and (5) to proposed § 1501.3(a)(1), (2), (4), and (4)(ii), respectively, and striking the remaining paragraphs. The 2020 regulations replaced the purpose section in 40 CFR 1501.1 with a list of factors agencies should consider in assessing whether NEPA applies or is otherwise fulfilled for a proposed activity or decision, and allows agencies to make these threshold considerations pursuant to their agency NEPA procedures or on an individual basis.

CEQ proposes to delete two of the threshold factors currently in 40 CFR 1501.1(a). First, CEQ proposes to delete the factor currently listed in 40 CFR 1501.1(a)(3), inconsistency with Congressional intent expressed in another statute. Upon further

[58] 2020 Final Rule, *supra* note 36, at 43319.

consideration, this factor may inadequately account for agencies' responsibility to harmonize NEPA with other statutes, as discussed further in section II.C.2. As discussed in section II.B.5, the regulations provide that an agency should determine if a statute or court exempts an action from NEPA or if compliance with NEPA and another statute would be impossible; if not, the agency must comply with NEPA. To the extent the factor suggests that Congress's intent regarding NEPA compliance involves considerations other than those two determinations, the factor is incorrect.

Second, CEQ proposes to strike the factor in 40 CFR 1501.1(a)(6) regarding functional equivalence. While certain Environmental Protection Agency (EPA) actions are explicitly exempted from NEPA's environmental review requirements, and courts have found other EPA-administered statutes to be functionally equivalent or otherwise exempt, CEQ considers this language added to the 2020 rule to go beyond the scope of the NEPA statute and case law because the language can be construed to expand functional equivalence beyond the narrow contexts in which it has been recognized. *See, e.g.,* 15 U.S.C. 793(c)(1) (exempting EPA actions under the Clean Air Act); 33 U.S.C. 1371(c)(1) (exempting most EPA actions under the Clean Water Act); *Env't Def. Fund, Inc.* v. *EPA,* 489 F.2d 1247, 1256–57 (D.C. Cir. 1973) (exempting agency actions under FIFRA); *W. Neb. Res. Council* v. *U.S. Env't Prot. Agency,* 943 F.2d 867, 871–72 (8th Cir. 1991) (noting exemptions under the Safe Drinking Water Act). CEQ considers the more appropriate and prudent approach is for agencies to establish mechanisms in their agency NEPA procedures to align processes and requirements from other environmental laws with the NEPA process.

CEQ proposes to eliminate the current language in 40 CFR 1501.1(b) allowing agencies to make threshold determinations individually or in their NEPA procedures because CEQ proposes to move the consideration of thresholds into § 1501.3 to consolidate the steps agencies should take to determine whether NEPA applies and, if so, what level of NEPA review is appropriate. The language in 40 CFR 1501.1(b) is also redundant to language in § 1507.3(d)(1), which would provide that agency NEPA procedures may identify activities or decisions that are not subject to NEPA. CEQ proposes to remove as unnecessary 40 CFR 1501.1(b)(1) because agencies have discretion to consult with CEQ and have done so for decades on a wide variety of matters, including on determining NEPA applicability, without such specific language in the CEQ regulations. Finally, CEQ proposes to eliminate 40 CFR 1501.1(b)(2) directing agencies to consult with another agency when they jointly administer a statute if they are making a threshold applicability determination. While CEQ agrees that consultation is a good practice in such circumstances, it does not consider such a requirement necessary for these regulations because consultation is best determined by the agencies involved.

2. Determine the Appropriate Level of NEPA Review (§ 1501.3)

CEQ proposes substantive revisions to § 1501.3 to provide a more robust and consolidated description of the process agencies should use to determine the appropriate level of NEPA review, including addressing the threshold question of whether NEPA applies. CEQ also proposes clarifying edits, including adding paragraph headings to paragraphs (a) through (d). This revised provision would clarify the steps for assessing the appropriate level of NEPA review, facilitating a more efficient and predictable review process.

First, as noted in section II.C.1, CEQ proposes to move 40 CFR 1501.1(a)(1) to a new § 1501.3(a), ''Applicability,'' and add a sentence requiring agencies to determine whether NEPA applies to a proposed activity or decision as a threshold matter. CEQ proposes this move because the inquiry into whether NEPA applies is central to determining the level of NEPA review and consolidating the steps in this process in one regulatory section would improve the clarity of the regulations. It is also consistent with the approach in section 106 of NEPA, which addresses threshold considerations. CEQ proposes to strike ''or is otherwise fulfilled'' in the moved text because, as discussed in section II.C.1, CEQ is proposing to remove the functional equivalence factor from the regulation.

Second, CEQ proposes to move the threshold determination factors agencies should consider when determining whether NEPA applies, currently at 40 CFR 1501.1(a)(1) and (2), to § 1501.3(a)(1) and (2) respectively. CEQ proposes to align the text in paragraph (a)(1) with the language in § 1500.6, ''exempted from NEPA by law,'' and align the text in paragraph (a)(2) with the language in section 106(a)(3) of NEPA, changing ''another statute'' to ''another provision of law'' for consistency with the statutory text. Third, CEQ proposes a new factor in paragraph (a)(3) to address circumstances other than those in which Congress or case law have exempted an activity from NEPA, to clarify that there must be an irreconcilable and fundamental conflict between complying with a statutory provision and complying with NEPA—*i.e.,* the other statutory provision must make NEPA compliance impossible. This factor would be consistent with case law and longstanding principles of statutory construction that require statutes to be read in harmony when it is possible to do so. This approach also reflects the statutory requirement of section 102 of NEPA that agencies interpret and administer ''the policies, regulations, and public laws of the United States'' in accordance with NEPA's policies and is consistent with CEQ's proposed revisions to § 1500.6, ''Agency Authority.'' 42 U.S.C. 4332; *see* section II.B.5.

Fourth, consistent with section 106(a)(1) and (4) of NEPA, CEQ proposes to move the threshold determination factors regarding whether the activity or decision is a major Federal action from 40 CFR 1501.1(a)(4) and (5), to § 1501.3(a)(4) and (a)(4)(ii), respectively. Consistent with section 106(a)(1) and (4) of NEPA, CEQ proposes to include whether an activity or decision is a final agency action or non-discretionary as subfactors of whether an activity or decision is a major Federal action in § 1501.3(a)(4) because these are also exclusions from the definition of a major Federal action. When agencies assess whether an activity or decision meets the definition of a major Federal action, agencies determine whether they have discretion to consider environmental effects consistent with § 1508.1(u). CEQ invites comment on whether it should make additional changes to § 1501.3(a) in light of the recently enacted provisions in section 106(a) regarding threshold determinations.

Fifth, CEQ proposes to move, with clarifying edits, 40 CFR 1501.9(e), ''Determination of scope,'' to a new proposed § 1501.3(b), ''Scope of action and analysis,'' to provide the next step in determining the appropriate level of NEPA review—the scope of the proposed action and its potential effects. In addition, CEQ proposes moving into § 1501.3(b) one sentence from 40 CFR 1502.4(a) directing agencies to evaluate in a single NEPA review proposals sufficiently closely related to be considered a single action, as well as text from 40 CFR 1501.9(e)(1) regarding connected actions, which are closely related Federal activities or decisions that agencies should consider in a single NEPA document. CEQ proposes to move

40 CFR 1501.9(e)(1)(i) through (e)(1)(iii) providing the types of connected actions into § 1501.3(b)(1)(i) through (b)(1)(iii), respectively. This longstanding principle from the 1978 regulations that agencies should not improperly segment their actions is relevant not only when agencies are preparing EISs; rather, it is critical for agencies to consider this as part of the determination whether to prepare an EA or apply a CE. CEQ proposes to consolidate this text into § 1501.3(b) because the determination of the scope of the action, including any connected actions, necessarily informs the appropriate level of NEPA review. While 40 CFR 1501.9(e) currently applies to the scope of EISs, CEQ's proposed consolidation would clarify that this analysis is applicable not only to the scope of the environmental document itself but also to the determination of the level of NEPA document the agency must prepare. Because including this provision in § 1501.3 would make it applicable to environmental reviews other than EISs, CEQ proposes to strike the sentence that accompanied the text in 40 CFR 1502.4(a) directing the lead agency to determine the scope and significant issues for analysis in the EIS as part of the scoping process. CEQ would retain in § 1502.4(a), ''Scoping,'' the requirement that agencies determine the scope and significant issues for analysis in an EIS using an early and open process. CEQ proposes in § 1501.3(b)(1)(i) to likewise change ''environmental impact statements'' to ''NEPA review.''

In bringing the text from 40 CFR 1501.9(e) to § 1501.3(b), CEQ is proposing to strike 40 CFR 1501.9(e)(2) and (3) relating to alternatives and impacts, respectively. The current CEQ regulations and the proposed revisions in this NPRM address the analyses of alternatives and effects regarding both EISs (§§ 1502.14, 1502.15) and EAs (§ 1501.5(c)(2)(ii) and (c)(2)(iii)). It would be premature in the process, unnecessary, and unhelpful to address alternatives as part of determining the level of NEPA review.

Sixth, CEQ proposes to redesignate 40 CFR 1501.3(a) as paragraph (c), title it ''Levels of NEPA review,'' and retain the existing paragraphs (1) through (3) without change. In paragraph (c), CEQ proposes to incorporate section 106(b)(3) of NEPA addressing the sources of information agencies may rely on when determining the appropriate level of NEPA review. While section 106(b)(3) only directly applies to an agency's determination whether to prepare an EA or an EIS, CEQ views the approach to reliable data and producing new research as consistent with longstanding practice and caselaw and appropriate to apply broadly to an agency's determination of the appropriate level of NEPA review, including a determination that no review is required. This approach avoids creating an implication that an agency could be required to conduct new research in a broader range of circumstances when making threshold determinations outside of whether to prepare an EA or EIS, for example in considering whether a CE applies. CEQ invites comment on this approach.

Seventh, CEQ proposes to redesignate 40 CFR 1501.3(b) as § 1501.3(d), title it ''Significance determination—context and intensity,'' and address factors agencies must consider in determining significance by restoring with some modifications the consideration of ''context'' and ''intensity'' from the 1978 regulations, which appeared in the definition of ''significantly.'' *See* 40 CFR 1508.27 (2019). Because this text provides direction on how agencies determine the significance of an effect, rather than a definition, this is a more appropriate location for this provision than § 1508.1.

CEQ proposes to modify the introductory language in § 1501.3(d) by requiring agencies to consider the context of an action and the intensity of the effects when considering whether the proposed action's effects are significant. CEQ proposes to strike the sentence requiring agencies to consider connected actions because this concept would be included in proposed paragraph (c).

Paragraph (d)(1) would restore the consideration of the context of the proposed action as a standalone consideration. Specifically, CEQ proposes to restore language from the 1978 regulations requiring agencies to analyze the significance of an action in several contexts. The proposed provision also provides some examples of contexts for consideration. First, the provision proposes agencies should consider the characteristics of the relevant geographic area such as proximity to unique or sensitive resources or vulnerable communities. Such resources may include historic or cultural resources, Tribal sacred sites, and various types of ecologically sensitive areas. This proposal relates to the intensity factor proposed in (d)(2)(iii), which CEQ is proposing to restore from the 1978 regulations. CEQ is proposing to include it as a context factor as well since it relates to the setting of the proposed action. It also would encourage agencies to consider proximity to communities with environmental justice concerns.

Second, CEQ proposes that agencies should consider the potential global, national, regional, and local contexts, which may be relevant depending on the scope of the action, consistent with the current regulations as well as the 1978 regulations. Third, agencies should consider the duration of the potential effects and whether they are anticipated to be short- or long-term. To that end, CEQ proposes to move and revise text providing that the consideration of short- and long-term effects is relevant to the context of a proposed action from current 40 CFR 1501.3(b)(2)(i) to paragraph (d)(1).

The 2020 rule narrowed the ''context'' consideration to the potentially affected environment in determining significance, stating that this reframing relates more closely to physical, ecological, and socio-economic aspects of the environment.[59] CEQ has reconsidered this approach and now finds it to be overly limiting. Agencies have decades of experience analyzing their actions within this broader framing of ''context.'' Moreover, this use of ''context'' is consistent with CEQ's 2022 reinstatement of the concepts of indirect and cumulative effects. Additionally, the 2020 rule's tying of significance to the affected environment, ''usually'' only in the local area,[60] could be read as deemphasizing reasonably foreseeable effects beyond the immediate area of the action. The appropriate environment is the one that the agency has identified as the affected environment in § 1502.15, which can include the global, national, regional, and local environment. For example, leases for oil and gas extraction or natural gas pipelines have local effects, but also have reasonably foreseeable global indirect and cumulative effects related to GHG emissions.

CEQ also proposes to reinstate ''intensity'' as a consideration in determining significance, which CEQ reframed in the 2020 rule as the ''degree'' of the action's effects. In § 1501.3(d)(2), CEQ proposes to require agencies to assess the intensity of effects from an action and to provide a list of factors, some or all of which may apply to any given action, for agencies to consider in relation to one another, returning to the approach from 1978. In 2020, CEQ justified the removal of intensity as a consideration in part

[59] 2020 Final Rule, *supra* note 36, at 43322.

[60] 40 CFR 1501.3(b)(1) (''For instance, in the case of a site-specific action, significance would *usually* depend only upon the effects in the local area.'') (emphasis added).

based on the proposition that effects are not required to be intense or severe to be considered significant.[61] However, the intensity factors that CEQ proposes to reinstate with modifications have long provided agencies with guidance in how the intensity of an action's effects may inform the significance determination. CEQ does not consider ''intense'' to be a synonym for ''significant;'' rather, it points to factors to inform the determination of significance that are part of longstanding agency practice. CEQ also proposes to clarify that agencies should focus on adverse impacts in determinations of significance. This is consistent with NEPA's policies and goals as set forth in section 101 of the statute. 42 U.S.C. 4331.

Paragraph (d)(2)(i) would mirror the 1978 rule's reference to beneficial effects with clarifying additions. CEQ proposes to state that only actions with significant adverse effects require an EIS. This is distinct from weighing beneficial effects against adverse effects to determine that an action's effects on the whole are not significant. Rather, this statement reflects the fact that an action with only beneficial effects and no significant adverse effects does not require an EIS, consistent with CEQ's proposed revisions to § 1501.3(d)(2), regarding the meaning of intensity.

CEQ proposes to add to paragraph (d)(2)(i) clarification that agencies should consider the duration of effects and provide an example of an action with short-term adverse effects but long-term beneficial effects. While significant adverse effects may exist even if the agency considers that on balance the effects of the action will be beneficial, the agency should consider any related short- and long-term effects in the same effect category together in evaluating intensity. For example, an agency should consider short-term construction-related GHG emissions from a renewable energy project in light of long-term reductions in GHG emissions when determining the overall intensity of effects. In this situation, the agency could reasonably determine that the climate effects of the proposed action would not be significantly adverse, and therefore an EIS would not be required. As another example, a forest restoration project may have a short-term adverse effect to a species by displacing it from the area while the project is carried out but have long-term beneficial effects to the species by reducing the risk that a severe wildfire will destroy the habitat altogether. An agency should consider both of these effects in assessing whether the action significantly affects the species, and may determine that the overall effects on the species would not be significantly adverse and therefore would not require an EIS.

In paragraph (d)(2)(ii), CEQ proposes to make a clarifying edit to the factor relating to the action's effects on health and safety by adding language indicating that the relevant consideration is ''the degree to which'' the proposed action may ''adversely'' affect public health and safety.

CEQ proposes to add in paragraph (d)(2)(iii) a factor to consider the degree to which the proposed action may adversely affect unique characteristics of the geographic area such as historic or cultural resources, Tribal sacred sites, parkland, and various types of ecologically sensitive areas. This would reinstate a factor from the 1978 regulations, with clarifying edits, which agencies have considered for decades. As noted earlier in this section, CEQ proposes to use the wording from the 1978 factor on unique characteristics because it is a context consideration. Consideration of this factor is consistent with both the definition of effects (§ 1508.1(g)) and the policies and goals of NEPA. 42 U.S.C. 4331.

In paragraph (d)(2)(iv), CEQ proposes to make a clarifying edit to the factor in 40 CFR 1501.3(b)(2)(iv) relating to actions that may violate Federal, State, Tribal, or local law by adding reference to ''other requirements.'' CEQ also proposes to include inconsistencies with policies designed for protection of the environment because agencies should not necessarily limit their inquiry to statutory requirements. Of course, it may be appropriate to give relatively more weight to whether the action threatens a law imposed for environmental protection as opposed to a policy, but policies imposed for the protection of clean air, clean water, or species conservation, for example, may nonetheless be relevant in evaluating intensity. CEQ invites comment on the inclusion of policies in this provision and whether the regulations should reference specific categories of policies.

Next, CEQ proposes to add paragraph (d)(2)(v) to consider the degree to which effects are highly uncertain. The 1978 regulations included factors for ''controversial'' effects and those that are ''highly uncertain or involve unique or unknown risks.'' CEQ proposes to restore a modified version of this concept that makes clear that the uncertainty of an effect is the appropriate consideration, and not whether an action is controversial. While a legitimate disagreement on technical grounds may relate to uncertainty, this approach would make clear that public controversy over an activity or effect is not a factor for determining significance.

CEQ proposes to add a factor to paragraph (d)(2)(vi) regarding the action's relationship with other actions. This would reinstate a factor from the 1978 regulations and reinforce the consideration of the scope of the action that agencies should consider in a NEPA document—that an agency cannot avoid significance by terming an action temporary when it is in fact a part of a repeating or ongoing action or segmenting it into smaller parts. This longstanding NEPA principle is consistent with decades of case law prohibiting the segmentation of actions. *See, e.g., Sierra Club* v. *Marsh,* 769 F.2d 868 (1st Cir. 1985); *Kern* v. *U.S. Bureau of Land Mgmt.,* 284 F.3d 1062 (9th Cir. 2002).

CEQ proposes to add a factor to paragraph (d)(2)(vii) relating to actions that would affect historic resources listed or eligible for listing in the National Register of Historic Places. This would generally reinstate a factor from the 1978 regulations, which agencies have decades of experience considering. Consideration of this factor furthers the policies and goals of NEPA, including to ''preserve important historic, cultural, and natural aspects of our national heritage . . . .'' 42 U.S.C. 4331.

CEQ proposes to add paragraph (d)(2)(viii) to include effects on an endangered or threatened species or its habitat, including critical habitat under the Endangered Species Act. 16 U.S.C. 1532(5). This would be an expansion of an intensity factor from the 1978 regulations, which only addressed critical habitat. CEQ's proposed revision would clarify that agencies should consider effects to the habitat of endangered or threatened species even if it has not been designated as critical habitat.

CEQ proposes to add paragraph (d)(2)(ix) to include consideration of the degree to which the action may have disproportionate and adverse effects on communities with environmental justice concerns. Evidence continues to accumulate that communities with environmental justice concerns often experience disproportionate environmental burdens such as pollution or urban heat stress, and often experience disproportionate health and other socio-economic burdens that make them more susceptible to adverse effects.

Finally, CEQ proposes to add paragraph (d)(2)(x) to include effects

[61] 2020 Final Rule, *supra* note 36, at 43322.

upon the rights of Tribal Nations reserved through treaties, statutes, or Executive Orders. This proposed addition would clarify that agencies should consider how an action may impact the reserved rights of Tribal Nations. Tribes' ability to exercise these rights often depends on protection of the resources that support the rights, and agencies should consider impacts to such resources. CEQ specifically seeks comments from Tribes on this proposed addition.

CEQ invites comments on whether there are other considerations that should be added to the regulations to guide agency evaluation of the context and intensity of an effect as part of a determination of significance.

3. Categorical Exclusions (§ 1501.4)

CEQ proposes revisions to § 1501.4 to clarify this provision, which the 2020 rule added, and provide agencies new flexibility to establish CEs using additional mechanisms and flexibilities outside of their NEPA procedures to promote more efficient and transparent development of CEs that may be tailored to specific environmental contexts or project types.

First, CEQ proposes to edit § 1501.4(a) for consistency with and add a cross reference to § 1507.3(c)(8), which currently requires agencies to establish CEs in their NEPA procedures. This revision would more fully and accurately reflect the purposes of and requirements for CEs. As is reflected in the regulations, CEQ views CEs to be an important mechanism to promote efficiency in the NEPA process where agencies have long exercised their expertise to identify and substantiate categories of actions that normally do not have a significant effect on the human environment.

CEQ also proposes to add the clause ''individually or in the aggregate'' to § 1501.4(a)'s description of CEs. This proposal would clarify that when establishing a CE in its procedures, an agency must determine that the application of the CE to a single action and the repeated collective application to multiple actions would not have significant effects on the human environment. This clarification recognizes that agencies often use CEs multiple times over many years. This change is consistent with the definition of ''categorical exclusion'' provided by section 111(1) as a ''category of actions,'' which highlights the manner in which CEs consider an aggregation of individual actions. This change is similar to the 1978 regulations' definition of CEs as categories of actions that do not ''individually or cumulatively'' have significant effects, which the 2020 rule removed consistent with its removal of the term ''cumulative impacts'' from the regulations. The Phase 1 rulemaking reinstated cumulative effects to the definition of ''effects,'' [62] so the 2020 rule's justification for removing the phrase no longer has a basis. However, CEQ proposes to use the phrase ''in the aggregate'' rather than ''cumulatively'' to avoid potential confusion. Cumulative effects refer to the incremental effects of an agency action added to the effects of other past, present, and reasonably foreseeable actions. In the context of establishing CEs, agencies must consider both the effects of a single action as well as the aggregation of effects from anticipated multiple actions covered by the CE such that the aggregate sum of actions covered by the CE does not normally have a significant effect on the human environment. As part of this analysis, agencies consider the effects—direct, indirect, and cumulative—of the individual and aggregated actions. Because the definition of effects includes cumulative effects, CEQ considers the phrase ''in the aggregate'' to more clearly define what agencies must consider in establishing a CE—the full scope of direct, indirect, and cumulative effects of the category of action covered by the CE. Agencies have flexibility on how to evaluate whether the ''aggregate'' of actions covered by a CE will not ordinarily have significant effects and may consider the manner in which the agency's extraordinary circumstances may avoid multiple potential actions having reasonably foreseeable significant effects in the aggregate. As discussed further in section II.I.2 CEQ notes that agencies do not need to evaluate the environmental effects of establishing the CE itself, but rather define the category of action and demonstrate in its substantiation that the CE does not normally have significant effects in the absence of extraordinary circumstances. CEQ proposes to add a qualifying clause at the end of the sentence to reference extraordinary circumstances consistent with § 1501.4(b), and add a definition of ''extraordinary circumstances'' at § 1508.1(m). These provisions are consistent with longstanding practice and recognize that, as the definition provided by section 111(1) indicates, CEs are a mechanism to identify categories of actions that normally do not have significant environmental effects. Extraordinary circumstances serve to identify actions within a category of actions the effects of which exceed those normally associated with that category of action and therefore, do not fall within the bounds of the CE.

Finally, CEQ also proposes to add at the end of paragraph (a) language clarifying that agencies may establish CEs individually or jointly with other agencies. In such cases, agencies may use a shared substantiation document and list the CEs in both agencies' NEPA procedures or identify them through another joint document as provided for by proposed § 1501.4(c). CEQ proposes this addition to provide an additional mechanism for establishing CEs transparently and with appropriate public process. Agencies may find value in establishing a CE jointly for activities that they routinely work on together where having a CE would create efficiency in project implementation. Agencies also may save administrative time by establishing CEs jointly.

CEQ proposes edits to § 1501.4(b)(1) to clarify the standard for applying a CE to a proposed action where extraordinary circumstances exist: an agency may apply a CE if the agency determines that a proposed action does not have the potential to result in significant effects, or the agency modifies the proposed action to address the extraordinary circumstance. This standard is consistent with agency practice and has been upheld in case law. As currently drafted, 40 CFR 1501.4(b)(1) could be construed to mean that agencies may mitigate extraordinary circumstances that would otherwise have the potential for significant effects and thereby apply a CE with no opportunity for public review or engagement on such actions. While the 2020 Response to Comments sought to distinguish ''circumstances that lessen the impacts'' from required mitigation to address significant effects,[63] based on CEQ's discussions with agency representatives and stakeholders, the potential for confusion remains. CEQ's proposed standard makes clear that if an extraordinary circumstance exists, an agency must make an affirmative determination that there is no potential for significant effects in order to apply a CE. If it finds such potential it must either: (1) modify its proposed action in a way that will address the extraordinary circumstance, or (2) prepare an EA or EIS.

CEQ also proposes to add a documentation requirement in these

[62] Phase 1 Final Rule, *supra* note 47, at 23469.

[63] CEQ, Update to the Regulations Implementing the Procedural Provisions of the National Environmental Policy Act Final Rule Response to Comments 130 (June 30, 2020) (''2020 Response to Comments''), *https://www.regulations.gov/document/CEQ-2019-0003-720629.*

instances where an agency is applying a CE notwithstanding extraordinary circumstances. CEQ also proposes to add language encouraging agencies to publish such documentation. While not required, CEQ encourages agencies to publish documentation of instances where an agency is applying a CE notwithstanding extraordinary circumstances to provide transparency to the public of an agency determination that there is no potential for significant effects. The proposed language responds to feedback from the public requesting such transparency. CEQ invites comment on whether it should require agencies to publish such documentation.

In addition, CEQ proposes to add a new § 1501.4(c) to provide agencies more flexibility to establish CEs outside of their NEPA procedures. This provision would allow agencies to establish CEs through a land use plan, a decision document supported by a programmatic EIS or EA, or other equivalent planning or programmatic decisions. Once established, agencies could apply CEs to future actions addressed in the program or plan, including site-specific or project-level actions. CEQ anticipates that expanding the mechanisms through which agencies may establish CEs will encourage agencies to conduct programmatic and planning reviews, increase the speed with which agencies can establish CEs while ensuring public participation and adequate substantiation, promote the development of CEs that are tailored to specific contexts, geographies, or project-types, and allow decision makers to consider the cumulative effects of related actions on a geographic area over a longer time frame than agencies generally consider in a review of a single action. This provision would not require agencies to establish CEs through the mechanism added in § 1501.4(c) but rather would provide new options for agencies to consider. CEQ also notes that this mechanism does not preclude agencies from conducting and relying on programmatic analyses in making project-level decisions consistent with § 1501.11. Additionally, it does not require agencies to conduct a NEPA analysis to establish CEs generally, consistent with § 1507.3(c)(8).

Establishing a CE through this alternative approach could be beneficial by providing agencies with more flexibility on how to identify categories of actions that normally will not have significant effects and establishing a CE for them. A programmatic EIS supporting a program decision or land use plan could, for example, provide the analysis necessary to substantiate a new CE established by the associated decision document that makes sense in the context of the overall program decision or land use plan. For example, a land management agency could consider establishing a CE for zero or minimal impact resilience-related activities. Enabling an agency to establish a CE through this mechanism would reduce duplication of effort by obviating the need for the agency to revise their NEPA procedures consistent with § 1507.3 after completing the programmatic EIS. Agencies also may find it efficient to establish a CE through a land use planning process rather than undertaking a separate process to establish the CE via agency procedures after completion of the land use planning process.

Paragraphs (c)(1) through (c)(6) would set forth the requirements for the establishment of CEs through mechanisms other than an agency's NEPA procedures. Paragraphs (c)(1) and (c)(2) would require agencies to provide CEQ an opportunity to review and comment and provide opportunities for public comment. Agencies may satisfy the requirement for notification and comment under paragraph (c)(2) by incorporating the proposed CEs into any interagency and public review process that involves notice and comment opportunities applicable to the relevant programmatic or planning document.

Proposed paragraphs (c)(3) and (c)(4) would include the same requirements for agencies to substantiate CEs and provide for extraordinary circumstances when they establish CEs under this section as when they establish CEs through their agency NEPA procedures pursuant to § 1507.3. Specifically, first, agencies would have to substantiate their determinations that the category of actions covered by a CE normally will not result in significant effects, individually or in the aggregate. Second, agencies would need to identify extraordinary circumstances. This could be the same list set forth in the agency's NEPA procedures, a list specific to this set of CEs, or a combination of both. While agencies would need to satisfy these requirements in a manner consistent with the establishment of CEs under § 1507.3, agencies could document their compliance with these requirements in the relevant programmatic or planning documents.

Proposed paragraph (c)(5) would direct agencies to establish a process for determining that a CE applies to a specific action in the absence of extraordinary circumstance, or determine the CE still applies notwithstanding the presence of extraordinary circumstances. Finally, paragraph (c)(6) would direct agencies to maintain a list of all such CEs on their websites, similar to the requirement for agencies to publish CEs established in their agency NEPA procedures consistent with §§ 1507.3(b)(2) and 1507.4(a). Agency websites should clearly link the CEs to their underlying programmatic or planning documents. Additionally, agencies may want to incorporate CEs established through these mechanisms into their agency NEPA procedures during a subsequent revision. CEQ encourages agencies to list all agency CEs in one location, regardless of how the agency established the CE, so that the public can easily access the full list of an agency's CEs.

Proposed § 1501.4(d) would identify a list of examples of features agencies may want to consider including when establishing CEs, regardless of what mechanism they use to do so. Paragraph (d)(1) would note that CEs may cover specific geographic areas or areas that share common characteristics, such as a specific habitat type for a given species.

To promote experimentation and evaluation, paragraph (d)(2) would indicate that agencies may establish CEs for a limited duration. Doing so would enable agencies to narrow the scope of analysis necessary to substantiate that a class of activities normally will not have a significant environmental effect where uncertainty exists about changes to the environment that may occur later in time that could affect the analysis. As with all CEs, agencies should review their continued validity periodically, consistent with CEQ's proposed review timeframe in § 1507.3(c)(9). Once the limited duration threshold is met, agencies could either consider the CE expired, conduct additional analysis to create a permanent CE, or reissue the CE for a new period.

Paragraph (d)(3) provides that a CE may include mitigation measures to address potential significant effects. A CE that includes mitigation is different than an agency modifying an action to avoid an extraordinary circumstance that would otherwise require preparation of an EA or EIS. Paragraph (d)(3) makes clear that an agency may establish a CE for a class of activities that include mitigation requirements as part of the CE application. Agencies would implement the activities covered by the CE as well as the mitigation incorporated into those activities as part of the CE. As an illustrative example, an agency could conclude that, as a category, a type of activity that degrades five acres of habitat will not ordinarily have significant effects where five acres

of equivalent habitat are effectively restored or conserved elsewhere. As another example, a CE could allow for vegetation management activities but require specific mitigation if a certain habitat type is disturbed, such as implementing vegetation activities on 10 acres of sage grouse habitat and requiring restoration or compensatory mitigation for an equivalent 10 acres of sage grouse habitat. Where an agency establishes a CE with a mitigation requirement, the agency would need to include such mitigation in their proposed actions in order for the CE to apply.

Paragraph (d)(4) would provide that agencies can include criteria for when a CE might expire, such that, if such criteria were present, the agency could no longer apply that CE. For example, an agency could establish a CE for certain activities up to a threshold, such as a specified number of acres or occurrences. Once the agency applied that CE up to the threshold number of proposed actions, the agency could no longer use the CE. An agency might set an expiration date or threshold where their record indicates a potential for significant effects after a certain number of applications of the CE to proposed actions; where there is uncertainty beyond that threshold; or where it is unclear how widely the agency would apply the CE. In other situations, an agency may want to make a CE time limited because its authority over the actions is likewise time limited.

Finally, CEQ proposes to strike the provision that would allow an agency to establish a process in its agency NEPA procedures to apply a CE listed in another agency's NEPA procedures in 40 CFR 1507.3(f)(5) and replace it with a provision in § 1501.4(e) that is consistent with the process for adoption established by section 109 of NEPA. While section 109 uses the term ''adopt'' CEQ is proposing to use ''apply'' to distinguish this provision from the longstanding use of ''adoption'' in the CEQ regulations to refer to an agency's reliance on another agency's previously completed analysis, including the determination that a CE applies to a proposed action.

First, paragraph (e)(1) would require the borrowing agency to identify the proposed action or category of proposed actions that falls within the CE. In instances where an agency would like to use the CE on a long-term basis, CEQ encourages agencies to establish the CE either in their own procedures or through the process set forth in § 1501.4(c). However, this provision would serve as an important bridge when agencies are implementing new programs where they have not yet established relevant CEs or when existing programs begin to undertake new categories of actions but where other agencies have experience with similar actions and have established a CE for those actions. In these circumstances, the agency could immediately begin to implement the new programs and new activities based on another agencies CE for similar actions without the need to first develop a CE to cover them. CEQ also notes that, consistent with the requirement of section 109(2) that an agency consult with ''the agency that established the categorical exclusion,'' this provision would only apply to CEs established administratively by the agency, including those that Congress directs agencies to establish administratively, but not those CEs created by statute. While CEQ encourages agencies to include legislative CEs established by statute in their NEPA procedures to provide transparency, they are not ''established'' by the agency, but rather by Congress. CEQ invites comment on this approach.

Second, under paragraph (e)(2), the borrowing agency would consult with the agency that has the listed CE to ensure application of the CE is appropriate. Third, under paragraph (e)(3), the borrowing agency would evaluate for extraordinary circumstances, consistent with § 1501.3(b) to incorporate the process for documenting use of the CE when extraordinary circumstances are present, but application of the CE is still appropriate. Finally, under paragraphs (e)(4) and (e)(5), the borrowing agency would document application of the CE, provide public notice of the CE that the agency plans to use, and publish the documentation of the application of the CE. Neither the statute or the proposed regulation requires the agency to accept comment on the public notice of the CE that the agency plans to use. In cases where an agency is applying CEs to a category of actions, the agency could conduct a single consultation and publish a consolidated notice, for example. CEQ invites comment on its proposed process. CEQ invites comment on whether the regulations implementing section 109 should include additional provisions to facilitate the use of CEs while ensuring CEs are not used improperly to authorize actions that have reasonably foreseeable significant effect.

CEQ notes that there has been some confusion regarding the difference between the use or borrowing of another agency's CE proposed in § 1501.4(e), which section 109 of NEPA refers to as adoption and is currently provided by 40 CFR 1507.3(f)(5) and adoption of a CE determination under § 1506.3(d). In the latter case of adoption of a CE determination, an agency with a CE has applied the CE to its own proposed action. A second agency then adopts that determination for the second agency's action that is substantially the same. Under § 1501.4(e), an agency may use a CE from another agency that has not itself determined that the CE applies to an action. In such circumstances, an agency would be borrowing the CE of another agency and applying it to a new, separate action, rather than adopting a CE determination for an action that is substantially the same.

4. Environmental Assessments (§ 1501.5)

CEQ proposes to revise § 1501.5 for consistency with sections 106(b)(2) and 107(e)(2) of NEPA, and to provide greater clarity to agencies on the requirements that apply to the preparation of EAs and to codify agency practice. CEQ proposes edits to address what agencies must discuss in an EA, how agencies should consider public comments they receive on draft EAs, what page limits apply to EAs, and what other requirements in the CEQ regulations agencies should apply to EAs.

Regarding the contents of an EA, CEQ proposes to split 40 CFR 1501.5(c)(2), which requires an EA to briefly discuss the purpose and need for the proposed action, alternatives, and effects, into paragraphs (c)(2)(i) through (iii) to improve readability and provide a clearly defined list of requirements. This formatting change would make it easier for the public and the agencies to ascertain whether an EA includes the necessary contents. For example, when an agency develops an EA for a proposal involving unresolved conflicts concerning alternative uses of available resources, section 102(2)(H) requires an analysis of alternatives, which will generally require analysis of one or more reasonable alternatives, in addition to a proposed action and no action alternative. 42 U.S.C. 4332(2)(H).

CEQ proposes to move from 40 CFR 1501.5(c)(2) into its own paragraph at § 1501.5(c)(3) the requirement for EAs to list the agencies and persons consulted in the development of the EA. CEQ also proposes to clarify in this paragraph that agencies include Federal agencies as well as State, Tribal, and local governments and agencies. CEQ also proposes to add in paragraph (c)(4) a requirement that the EA include a unique identification number that can be used for tracking purposes that

would then be carried forward to all other documents related to the environmental review of the action, including the FONSI. Identification numbers can help the public and agencies track the progress of an EA for a specific action as it moves through the NEPA process and may allow for more efficient and effective use of technology such as databases. CEQ also is proposing a similar requirement for EISs in § 1502.4(e)(9).

To reflect current agency practice and provide the public with a clearer understanding about potential public participation opportunities with respect to EAs, CEQ proposes to add a new paragraph (e) that provides that if an agency chooses to publish a draft EA, it must invite public comment on the draft and consider those comments when preparing a final EA. This provision reflects the fact that one of the primary purposes for which agencies choose to prepare draft EAs is to enable public participation. Codifying this practice will enhance the public's understanding of the NEPA process and meaningful public engagement and does not restrict agency discretion over whether to choose to prepare a draft EA for public comment. CEQ would redesignate the current 40 CFR 1501.5(e) and (f) to § 1501.5(f) and (g) respectively.

CEQ also proposes to revise § 1501.5(g) to dispense with the requirement for senior agency official approval to exceed 75 pages, not including any citations or appendices, for consistency with section 107(e)(2) of NEPA.

CEQ proposes to add paragraph (h) to clarify that agencies may reevaluate or supplement an EA if a major Federal action remains to occur and the agency considers it appropriate to do so. Paragraph (h) also would provide that agencies may reevaluate an environmental assessment or otherwise document a finding that changes to the proposed action or new circumstances or information relevant to environmental concerns are not substantial, or the underlying assumptions of the analysis remain valid. CEQ adds this to clarify that an agency may apply the provisions at § 1502.9 regarding supplemental EISs to a supplemental EA to improve efficiency and effectiveness.

Finally, CEQ proposes to clarify the provisions that agencies should or may apply to EAs. In a new paragraph (i), CEQ proposes to clarify that agencies generally should apply the provisions of § 1502.21 regarding incomplete or unavailable information and § 1502.23 regarding scientific accuracy. The 2020 regulations added these as provisions agencies ''may apply;'' however, on reflection, CEQ considers it important to disclose where information is incomplete or unavailable, and ensure scientific accuracy for all levels of NEPA review, not just EISs. Then, CEQ proposes to provide in paragraph (j) that agencies may apply the other provisions of parts 1502 and 1503 where they consider it appropriate to improve efficiency and effectiveness of EAs. This provision includes a list of example provisions where this might be the case—scoping (§ 1502.4), cost-benefit analysis (§ 1502.22), environmental review and consultation requirements (§ 1502.24), and response to comments (§ 1503.4).

5. Findings of No Significant Impact (§ 1501.6)

CEQ proposes two revisions to § 1501.6 on findings of no significant impact (FONSIs) to clarify the 2020 rule's codification of the longstanding agency practice of relying on mitigated FONSIs in circumstances where the agency incorporates mitigation into the proposed action to reduce its effects below significance. This is an important efficiency tool for NEPA compliance because it expands the circumstances in which an agency may prepare an EA and reach a FONSI, rather than preparing an EIS, consistent with the requirements of NEPA.

Paragraph (a) currently describes that an agency prepares a FONSI when it determines, as a result of an EA, not to prepare an EIS because the proposed action will not have significant effects. At the end of paragraph (a), CEQ proposes to clarify that agencies can prepare a mitigated FONSI if the action will include mitigation to avoid the significant effects that would otherwise occur or minimize or compensate for them to the point that the effects are not significant. So long as the agency can conclude that effects will be insignificant in light of mitigation, the agency can issue a mitigated FONSI. CEQ considers this an important clarification for consistency with the language in § 1501.6(c). Codification of these best practices also aligns with guidance CEQ has issued on appropriate use of mitigation, monitoring, and mitigated FONSIs.[64]

Paragraph (c) currently addresses what an agency must include in a FONSI regarding mitigation. The text provides that when an agency relies on mitigation to reach a FONSI, the mitigated FONSI must state the enforceable mitigation requirements or commitments that avoid the potentially significant effects. CEQ proposes to clarify in the second sentence that the FONSI must state the enforceable mitigation requirements or commitments, as well as the authorities for them, since they must be enforceable for agencies to reach a mitigated FONSI. CEQ proposes this change because, where a proposed action evaluated in an EA may have significant effects, and an agency is not preparing an EIS, the FONSI must include mitigation of the significant effects. At the end of paragraph (c), CEQ proposes additional language to provide additional details on what is needed to demonstrate that mitigation requirements or commitments are enforceable. Specifically, the proposed language would direct agencies to identify the authority that is being exercised to make the mitigation enforceable.

Finally, as discussed in section II.G.2, CEQ proposes to add a new sentence at the end of paragraph (c) to require a monitoring and compliance plan when the EA relies on mitigation as a component of the proposed action and incorporates the mitigation into the FONSI, consistent with proposed § 1505.3(c). These changes will help effectuate NEPA's purpose as articulated in section 101, including to ''attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences'' and to ''preserve important historic, cultural, and natural aspects of our national heritage . . . .'' 42 U.S.C. 4331(b).

6. Lead Agency; Cooperating Agencies (§§ 1501.7 and 1501.8)

CEQ proposes to eliminate the reference to ''complex'' environmental assessments. The 2020 rule added this term without definition. CEQ invites comment on whether it should retain a complex EA in the regulations, and if so, how CEQ should define a complex EA.

CEQ proposes to retitle § 1501.7 ''Lead Agency'' to align with section 107(a) of NEPA. CEQ proposes to revise paragraph (b) regarding joint lead agencies for consistency with section 107(a)(1)(B) of NEPA to clarify that the participating Federal agencies may designate a Federal, State, Tribal, or local agency as a joint lead agency upon invitation to and acceptance by such agency. CEQ includes Federal agencies in the list of potential joint lead agencies because there are circumstances in which having another

[64] CEQ, Appropriate Use of Mitigation and Monitoring and Clarifying the Appropriate Use of Mitigated Findings of No Significant Impact (Jan. 14, 2011), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/Mitigation_and_Monitoring_Guidance_14Jan2011.pdf.*

agency serving as a joint lead agency will enhance efficiency. CEQ does not read the text in section 107(a)(1)(B) of NEPA as precluding this approach, but rather Congress specified that State, Tribal, and local agencies may serve as joint lead agencies because they are ineligible to serve as the lead agency. CEQ invites comment on whether it should make additional changes to this paragraph.

CEQ proposes to revise paragraph (c) for consistency with section 107(a)(1) of NEPA to clarify that the participating Federal agencies determine the agency that will be lead and any joint lead agencies, and that the lead agency determines any cooperating agencies. This change also would make this paragraph consistent with the text in § 1506.2(c) on joint EISs. In § 1501.7(d), CEQ proposes to revise the text for consistency with section 107(a)(5)(B) of NEPA and make a non-substantive change to replace the phrase ''private person'' with the word ''individual'' for consistency with this term's use in other sections of the regulations. In paragraph (e), CEQ proposes to revise the text for consistency with section 107(a)(4) of NEPA, clarify that the 45 days is calculated from the date of the written request to the senior agency officials as set forth in § 1501.7(d), and replace ''persons'' with ''individuals'' for consistency with the rest of regulations.

In paragraph (f), CEQ proposes to revise the text for consistency with section 107(a)(5)(D) of NEPA, to change ''within 20 days'' to ''no later than 20 days'' in the first sentence, and ''20 days'' to ''40 days'' and ''determine'' to ''designate'' in the second sentence.

Currently, 40 CFR 1501.7(g), addressing combined documents, is consistent with the text of section 107(b) of NEPA with respect to EISs, EAs, and FONSIs. The statute does not address joint RODs. CEQ proposes to revise § 1501.7 to add a caveat that agencies must issue joint RODs except where it is inappropriate or inefficient to do so, such as when an agency has a separate statutory directive, or it would take significantly longer to issue a joint ROD than separate ones. CEQ recognizes that, in some cases, requiring a joint ROD could inadvertently slow the NEPA process down because, for example, agencies may have different procedures for issuing authorizations under their applicable legal authorities or may need to consider different factors. But in other cases, it could improve efficiency by avoiding duplication of effort or analysis. Additionally, for consistency with § 1501.5, CEQ proposes to add that agencies can jointly determine to prepare an EIS if a FONSI is inappropriate.

In § 1501.7(h)(2), CEQ proposes to add a clause consistent with section 107(a)(2)(C) of NEPA requiring the lead agency to give consideration to a cooperating agency's analyses and proposals. In the existing clause, CEQ proposes to move the qualifier, ''to the extent practicable'' to clarify that it only modifies the second clause, and change ''proposals'' to ''information'' to make the text consistent with § 1501.8(b)(3). Further, the use of ''proposal'' here is inconsistent with the definition of ''proposal'' provided in § 1508.1(cc). CEQ also proposes to remove the reference to jurisdiction by law or special expertise as unnecessarily redundant given that the definition of ''cooperating agencies'' in § 1508.1(e) incorporates those phrases.

As discussed further in section II.C.8, CEQ proposes to move the requirements for schedules and milestones currently in 40 CFR 1501.7(i) and (j) to proposed § 1501.10(c) in order to consolidate provisions related to deadlines, schedules, and milestones in one section.

CEQ proposes an addition to § 1501.8 to clarify the meaning of the phrase ''special expertise.'' Paragraph (a) provides that a lead agency may request an agency with special expertise to serve as a cooperating agency. CEQ proposes to clarify in paragraph (a) that special expertise can include Indigenous Knowledge. This proposed change helps ensure that Federal agencies respect and benefit from unique knowledge that Tribal governments may bring to the environmental review process. CEQ notes that the Office of Science and Technology Policy and CEQ have issued a Guidance Memorandum for Federal Departments and Agencies on Indigenous Knowledge,[65] but does not define Indigenous Knowledge. CEQ invites comment on whether it should include such a definition in the regulations. Finally, CEQ notes that even where a federally recognized Tribe participates as a cooperating agency, the agency also may have an obligation to engage in government-to-government consultation on the proposed action consistent with the agency's obligations under E.O. 13175, *Consultation and Coordination with Indian Tribal Governments.*[66]

In paragraph (b)(7), CEQ proposes to strike the second clause requiring cooperating agencies to limit their comments to align this paragraph with section 107(a)(3) of NEPA. Finally, CEQ invites comment on whether it should make any additional changes to these sections to promote or improve lead and cooperating agency engagement on the preparation of NEPA documents or increase the efficiency of the preparation process.

7. Public and Governmental Engagement (§ 1501.9)

CEQ proposes to address public and governmental engagement in a revised § 1501.9 by moving and updating 40 CFR 1506.6, ''Public involvement,'' to § 1501.9, and moving provisions specific to the EIS scoping process to § 1502.4. CEQ proposes these updates to continue to provide agencies with flexibility to tailor their engagement specific to their programs and actions while also maintaining the requirements to engage the public and affected parties in the NEPA process. CEQ proposes revisions to § 1501.9 to emphasize the importance of creating an accessible and transparent NEPA process. CEQ also proposes many of these changes in response to feedback on the Phase 1 proposed rule, the 2020 proposed rule, and input received from stakeholders and agencies during development of this proposed rule. Much of that feedback requested increased opportunities for public engagement and increased transparency about agency decision making, along with general requests that CEQ elevate the importance of public engagement in the NEPA process. Finally, CEQ proposes to move the requirements related to public engagement to part 1501 to emphasize that it is a core component of the NEPA process and agency planning, regardless of the level of NEPA analysis being undertaken.

To accomplish this goal, CEQ is proposing changes to multiple sections of the regulations. First, CEQ is proposing to move the existing provisions of 40 CFR 1501.9 on scoping, specifically paragraphs (a), (b), (c), (d), (d)(1) through (8), (f), and (f)(1) through (5) to proposed § 1502.4, ''Scoping.'' As discussed in sections II.C.2 and II.C.9, CEQ proposes to move the existing provisions in 40 CFR 1502.4 on ''Major Federal actions requiring the preparation of environmental impact statements'' to §§ 1501.3 and 1501.11. Also, as discussed in section II.C.2, CEQ proposes to move the remaining text of existing 40 CFR 1501.9(e) and (e)(1) through (3) on the determination of scope to proposed § 1501.3 because

[65] Office of Science and Technology Policy and CEQ, Guidance for Federal Departments and Agencies on Indigenous Knowledge (Nov. 30, 2022), *https://www.whitehouse.gov/wp-content/uploads/2022/12/OSTP-CEQ-IK-Guidance.pdf.*

[66] E.O. 13175, *supra* note 53.

determining the scope of actions applies to all levels of NEPA review.

CEQ proposes to retitle § 1501.9 to ''Public and governmental engagement'' and accordingly update references to ''public involvement'' within this section and throughout the CEQ regulations to ''public engagement.'' CEQ is proposing this change because the word ''engagement'' better reflects how Federal agencies should be interacting with the public. The word ''engagement'' reflects a process that is more interactive and collaborative compared to simply including or notifying the public of an action. Engagement is also a common term for Federal agencies with experience developing public engagement strategies or that work with public engagement specialists. CEQ proposes to add ''governmental'' to the title to better reflect the description of the provisions proposed to be included in the section, which relate to both public and governmental entities.

Next, CEQ proposes to add paragraphs (a) and (b) to articulate the purposes of public and governmental engagement and to identify the responsibility of agencies to determine the appropriate methods of public and governmental engagement and conduct scoping consistent with § 1502.4 for EISs. CEQ proposes to use the phrase ''meaningful'' engagement to better describe the purpose of this process because public and governmental engagement should not be a mere check-the-box exercise, and agencies should conduct engagement with appropriate planning and active dialogue or other interaction with stakeholders in which all parties can contribute. For example, such engagement can inform the potential for significant effects or identify alternatives that avoid or reduce effects. Agencies should determine the appropriate level of outreach needed to engage meaningfully and effectively with affected communities.

Paragraph (c) would list what actions the lead agency should take when conducting outreach for public and governmental engagement. Proposed paragraph (c)(1) would recommend agencies invite likely affected agencies and governments, and paragraph (c)(2) would recommend agencies conduct early engagement with likely affected or interested members of the public. CEQ modeled these provisions on the existing approaches in 40 CFR 1501.7(a)(1) (2019) and 40 CFR 1501.9(b) (2020) to invite early participation of likely affected parties. Paragraph (c)(3) would provide flexibility to agencies to tailor engagement strategies, considering the scope, scale, and complexity of the proposed action and alternatives, the degree of public interest, and other relevant factors. CEQ proposes to move from 40 CFR 1506.6(c) to § 1501.9(c)(3) the requirement that agencies consider the ability of affected parties to access electronic media when selecting the appropriate methods of notification. CEQ also proposes to add a clause to the end of paragraph (c)(3) to require agencies to consider the primary language of affected persons when determining the appropriate notification methods to use.

CEQ then proposes to move and modify the rest of 40 CFR 1506.6 to proposed §§ 1501.9(d), (e), and (f). Specifically, CEQ proposes to move the introductory clause of 40 CFR 1506.6 and 40 CFR 1506.6(b), including its paragraphs, to § 1501.9(d) and (d)(2), respectively, and make minor revisions to improve readability and consistency with the rest of § 1501.9, including adding the paragraph heading ''notification.'' CEQ also proposes in (d)(2) to clarify that agencies should make environmental documents available, as appropriate, to help inform the public engagement process. CEQ proposes here and throughout the CEQ regulations to replace the word ''notice'' with ''Notification,'' except where ''notice'' is used in reference to a **Federal Register** notice. This proposed change is intended to clearly differentiate between those requirements to publish a notice in the **Federal Register** and other requirements to provide notification of an activity, which may include a notice in the **Federal Register** or use of other mechanisms.

CEQ proposes a new paragraph (d)(1) to require agencies to publish notification of proposed actions they are analyzing through an EIS. CEQ proposes this requirement in response to feedback from multiple stakeholders and members of the public requesting more transparency about agency proposed actions. Agencies may publish notification through websites, email notifications, or other mechanisms such as the Permitting Dashboard,[67] so long as the notification method or methods are designed to adequately inform the persons and agencies who may be interested or affected, consistent with the definition of ''publish'' in § 1508.1(ee). A notice of intent in the **Federal Register**, consistent with § 1502.4(e), can fulfill the notification requirement, but agencies also may elect to use additional notification methods. CEQ proposes to combine the provisions from 40 CFR 1506.6(b)(3)(i) and (ii) on notice to State, Tribal, and local governments and agencies in proposed § 1501.9(d)(2)(iii)(A) to consolidate similar provisions. CEQ also proposes to recommend in paragraph (d)(2)(iii)(I) that agencies establish email notification lists or similar methods for the public to easily request electronic notifications for proposed actions.

As discussed in section II.I.3, CEQ proposes to move the requirement for agencies to explain in their NEPA procedures where interested persons can get information on EISs and the NEPA process from 40 CFR 1506.6(e) to § 1507.3(c)(11) since this is a requirement for NEPA procedures, not public engagement. CEQ proposes to move the requirements to make EISs available under FOIA from 40 CFR 1506.6(f) to § 1501.9(d)(3).

CEQ proposes to delete 40 CFR 1506.6(d) on soliciting information from the public because CEQ proposes to include that concept in the purpose and language of § 1501.9. CEQ proposes to move 40 CFR 1506.6(c) on public meetings and hearings to § 1501.9(e), with modification, including adding the heading ''Public meetings and hearings'' to the paragraph, making minor revisions for clarity, consistency, and readability, and adding a phrase to clarify that when an agency accepts comments for electronic or virtual meetings, agencies must allow the public to submit them electronically or via regular mail. CEQ also proposes to add in paragraph (e) a sentence encouraging agencies to consider the needs of affected communities when determining what format to use for a public hearing or public meeting because the best option for the communities involved may vary.

Finally, CEQ proposes to move 40 CFR 1506.6(a) on public involvement for NEPA procedures to new paragraph § 1501.9(f), adding a paragraph heading ''Agency procedures'' and changing the word ''involve'' to ''engage.'' CEQ is proposing to move this provision to its own paragraph because engagement in the development of agency NEPA procedures does not align with the new title added for paragraph (d) and its paragraphs on notification requirements.

CEQ invites comment on whether and how it can make any additional changes to this or other provisions in the regulations to enhance community engagement. This could include adding provisions to the NEPA regulations to

[67] *See* Fed. Permitting Improvement Steering Council, Permitting Dashboard for Federal Infrastructure Projects, *https://www.permits.performance.gov/.*

further address the responsibilities of the Chief Public Engagement Officers proposed in § 1507.2(a) to facilitate community engagement across the agency and technical assistance to communities. CEQ welcomes other ideas.

8. Deadlines and Schedule for the NEPA Process (§ 1501.10)

CEQ proposes to retitle § 1501.10 to ''Deadlines and schedule for the NEPA process'' and revise the section to direct agencies to set deadlines and schedules for NEPA reviews to achieve efficient and informed NEPA analyses consistent with section 107 of NEPA. The proposed changes in this section would improve transparency and predictability for stakeholders and the public regarding NEPA reviews.

In paragraph (a), CEQ proposes edits to emphasize that while NEPA reviews should be efficient and expeditious, they also must include sound analysis. The proposal would direct agencies to set deadlines and schedules tailored to individual or types of proposed actions to facilitate meeting the deadlines proposed in § 1501.10(b). Consistent with section 107(a)(2)(D) of NEPA, CEQ also proposes in this paragraph to require, where applicable, the lead agency to consult with and seek concurrence of joint lead, cooperating, and participating agencies and consult with project sponsors and applicants when establishing and updating schedules.

CEQ proposes to update paragraph (b) for consistency with section 107(h) of NEPA. Paragraph (b)(1) would require agencies to complete an EA within one year and paragraph (b)(2) would require EIS completion in two years unless the lead agency extends the deadline in consultation with any applicant or project sponsor and sets a new deadline. In circumstances where there is no applicant or project sponsor, the consultation requirement is inapplicable to extension of deadlines. Paragraph (b)(3) would identify the starting points from which the deadline is measured and require agencies to measure from the soonest of the three dates identified in section 107(g) of NEPA, as applicable. CEQ notes that section 107(g)(3) of NEPA provides a mechanism for project sponsors to petition the courts for relief if an agency fails to meet the deadlines. Finally, paragraph (b)(4) would require agencies to submit the report to Congress on any missed deadlines required by section 107(h) of NEPA.

To enhance predictability, CEQ proposes to add a new paragraph (c), which would contain text moved from 40 CFR 1501.7(i) and modified for consistency with section 107(a)(2)(D) and (E) of NEPA requiring the lead agency to develop schedules for EISs and EAs. The schedule would include key milestones for the environmental review process, including reviews, permits, and authorizations, and the lead agency would develop it in consultation with the applicant or project sponsor and in consultation with and seek the concurrence of any joint lead, cooperating, and participating agencies. CEQ proposes to allow schedules to be tailored to proposed actions and to highlight factors that may help agencies set specific schedules to meet the deadlines. Finally, CEQ proposes to move to the end of this paragraph text from 40 CFR 1501.7(j) with modifications, including for consistency with section 107(a)(2)(E) of NEPA, and provide clarification to enhance interagency communication and issue resolution. The proposed changes would require that, when the lead agency or any participating agency anticipates a missed milestone, that agency notifies the responsible agency (and the lead agency if identified by another agency) and request that they take action to comply with the schedule. To emphasize the importance of informed and efficient decision making, CEQ proposes to require agencies to elevate any unresolved disputes contributing to the missed milestone to the appropriate officials for resolution within the deadlines for the individual action.

CEQ proposes to redesignate 40 CFR 1501.10(c) as paragraph (d), which addresses factors in setting deadlines, and make changes to the text for consistency with the proposed changes to paragraph (b). Specifically, CEQ proposes to change the reference to ''deadlines'' to add a reference to ''the schedule'' and add a reference to the ''lead agency,'' to consider the listed factors in setting schedules. CEQ proposes to add an additional factor to (d)(7), redesignating 40 CFR 1501.10(c)(7) to be paragraph (d)(8), to add the degree to which a substantial dispute exists on the proposed action and its effects. This would restore and clarify a factor included in the 1978 regulations at 40 CFR 1501.8(a)(vii) (2019) regarding the degree to which the action is controversial. While the 2020 regulations removed this factor because it overlapped with other factors, CEQ is proposing to restore and clarify it in the list of factors, focusing on substantial disputes over the size, location, nature, or consequences of the proposed action and its effects. CEQ considers this an important factor that could have implications for establishing schedules and milestones. In such instances, agencies should seek ways to resolve disputes early in the process, including using conflict resolution and other tools, to achieve efficient outcomes and avoid costly and time-consuming litigation later in the process.

CEQ proposes to redesignate 40 CFR 1501.10(d) as paragraph (e) and require a schedule to include a list of specific milestones. Proposed paragraphs (e)(1) through (e)(5) would require EIS schedules to include proposed dates for publication of the NOI, issuance of the draft EIS, the public comment period, issuance of the final EIS, and issuance of the ROD. CEQ proposes to remove paragraphs 40 CFR 1501.10(d)(2), (d)(6), and (d)(7) because they are either covered by proposed (e)(1) through (e)(3) or unnecessary. CEQ proposes in paragraph (f) and (f)(1) through (f)(4) to identify the milestones that agencies must include in schedules for EAs.

CEQ proposes to redesignate 40 CFR 1501.10(e) as paragraph (g). Finally, to increase predictability and enhance agency accountability, CEQ proposes to strike 40 CFR 1501.10(f) and add a new paragraph (h) to require agencies to make schedules for EISs publicly available and to publish revisions to the schedule. It also would require agencies to publish revisions to the schedule and include an explanation for substantial revisions to increase transparency and public understanding of decision making and to encourage agencies to avoid unnecessary delays.

9. Programmatic Environmental Document and Tiering (§ 1501.11)

CEQ proposes to revise and retitle § 1501.11, ''Programmatic environmental document and tiering,'' for consistency with section 108 of NEPA, to consolidate relevant provisions, and to add new language to codify best practices for developing programmatic NEPA reviews and tiering, which are important tools to facilitate more efficient environmental reviews and project approvals. The revisions to this section propose to move portions of 40 CFR 1502.4 on EISs for broad Federal actions to proposed § 1501.11 because agencies can review actions at a programmatic level in both EAs and EISs. CEQ has encouraged agencies to engage in environmental reviews for broad Federal actions through the NEPA process since CEQ's initial guidelines. This continues to be a best practice for addressing broad actions, such as programs, policies, rulemakings, series of projects, and larger or multi-phase projects. CEQ developed guidance in 2014 on Effective

Use of Programmatic NEPA Reviews,[68] compiling best practices across the Federal Government on the development of programmatic environmental reviews. In this proposed rule, CEQ would codify some of these principles.

CEQ proposes to first address programmatic environmental documents and then tiering in § 1501.11. Accordingly, CEQ proposes to redesignate existing 40 CFR 1501.11(a), (b), and (c), which address tiering, to be proposed paragraphs (b), (b)(1), and (b)(2), respectively, with some modifications. CEQ proposes to add a new paragraph (a) to address programmatic environmental documents. Proposed paragraph (a) would encourage the use of programmatic environmental documents through an EIS or EA that evaluates the environmental effects of policies, programs, plans, or groups of related activities. CEQ proposes to move text from 40 CFR 1502.4(b) to § 1501.11(a) and revise it to include EAs, providing that programmatic environmental documents should be relevant to the agency decisions and timed to coincide with meaningful points in agency planning and decision making. Finally, paragraph (a) would clarify that agencies can use programmatic environmental documents in a variety of ways, highlighting some examples for agencies to consider to facilitate better and more efficient environmental reviews.

CEQ proposes to move the list of ways agencies may find it useful to evaluate a proposal when preparing programmatic documents from 40 CFR 1502.4(b)(1) and (b)(1)(i) through (b)(1)(iii) to § 1501.11(a)(1) and (a)(1)(i) through (a)(1)(iii), respectively, and expand the list to apply to environmental documents rather than just EISs to encompass EAs. CEQ proposes to modify paragraph (a)(1)(ii) to clarify ''[g]enerically'' to mean ''[t]hematically or by sector,'' and add technology as an example action type.

CEQ proposes to add paragraph (a)(2) to provide examples of the types of agency actions that may be appropriate for programmatic environmental documents, including programs, policies, or plans; regulations; national or regional actions; or actions with multiple stages and are part of an overall plan or program. CEQ proposes to move 40 CFR 1502.4(b)(2) to § 1501.11(a)(3) and recommend that agencies employ scoping and other tools to describe the relationship between programmatic environmental document and related actions to reduce duplication. CEQ proposes to strike the last sentence of 40 CFR 1502.4(b)(2) stating that agencies may tier their analyses because tiering and programmatic environmental documents would now be addressed together in this section rendering the language unnecessary.

As referenced earlier in this section, CEQ proposes to redesignate the existing paragraphs on tiering to paragraphs (b), (b)(1) and (b)(2). CEQ proposes to title paragraph (b) ''Tiering'' and add new language to describe when agencies may employ tiering. CEQ proposes to strike as redundant the reference to issues not yet ripe for decision as well as the last sentence on applying tiering to different stages of actions.

In § 1501.11(b)(1) CEQ proposes to add programmatic environmental document to the list of documents from which agencies may tier. This paragraph also would clarify that agencies need to discuss the relationship between the tiered analysis and the previous review; evaluate site-, phase-, or stage-specific conditions and effects; and allow for public engagement opportunities that are appropriate for the location, phase, or stage.

Programmatic documents can most effectively address later activities when they provide a description of planned activities that would implement the program and consider the effects of the program as specifically and comprehensively as possible. A sufficiently detailed programmatic analysis with such project descriptions can allow agencies to rely upon programmatic environmental documents for further actions with no or little additional environmental review necessary. When conducting programmatic analyses, agencies should engage the public throughout the NEPA process and consider when it is appropriate to re-engage the public prior to implementation of the action.

In paragraph (c), CEQ proposes to include the provisions in section 108 of NEPA, which address when an agency may rely on a programmatic document in subsequent environmental documents. CEQ notes that it interprets the reference to ''judicial review'' in paragraph (c)(1) to mean an opportunity for a party to challenge the programmatic document, including an administrative proceeding or challenge under the Administrative Procedure Act. CEQ invites comment on whether to provide additional information in the regulations to clarify this provision. CEQ proposes in paragraph (c)(2) to require agencies to briefly document their reevaluations when relying on programmatic environmental documents older than 5 years. CEQ invites comment on whether and how to more closely align this provision with the reevaluation and supplementation provisions in §§ 1501.5(h) and 1502.9(d).

CEQ invites comment on any additional changes that would promote effective use of programmatic environmental reviews to facilitate efficient and non-duplicative subsequent review of project-specific actions, including through tiering.

10. Incorporation by Reference Into Environmental Documents (§ 1501.12)

CEQ proposes minor modifications to § 1501.12 to emphasize the importance of transparency and accessibility of material that agencies incorporate by reference. CEQ proposes to add a specific requirement for agencies to briefly explain the relevance of any material incorporated into the environmental document to clarify that agencies must do this. CEQ proposes this addition because explaining the relevance of incorporated material in addition to summarizing it will better inform the decision maker and the public. CEQ encourages agencies to integrate the description of relevance into the summary of the material. CEQ also proposes to change ''may not'' to ''shall not'' to eliminate a potential ambiguity over whether agencies must make material they incorporate by reference reasonably available for public inspection. CEQ also proposes to add a reference to ''publicly accessible website'' as an example of a mechanism for making material incorporated by reference available to the public, and clarify that an agency may meet this obligation by posting documents on a website. Finally, CEQ proposes to add language encouraging agencies to provide digital references, such as hyperlinks, to incorporated material or otherwise indicate how the public can access the material for inspection.

D. Proposed Revisions To Update Part 1502, Environmental Impact Statements

CEQ is proposing revisions to many sections of part 1502. CEQ is not proposing any substantive changes to § 1502.3, but is revising the section title to read ''Statutory requirements for environmental impact statements.'' CEQ is not proposing substantive changes to § 1502.6, Interdisciplinary preparation; § 1502.13, Purpose and need; § 1502.18, List of preparers; § 1502.19, Appendix; § 1502.20, Publication of the environmental impact statement; § 1502.22, Cost-benefit analysis; or

[68] Programmatic Guidance, *supra* note 11.

§ 1502.24, Environmental review and consultation requirements. CEQ invites comment on whether it should make any changes to these sections or other changes to part 1502.

CEQ particularly invites comment on whether it should codify any or all of its 2023 GHG guidance, and, if so, which provisions of part 1502 or other provisions of the regulations CEQ should amend. CEQ proposes to incorporate some or all of the 2023 GHG guidance, which would require making additional changes in the final rule to codify the guidance in whole or part, as is or with changes, based on the comments CEQ receives on this proposed rule.[69]

1. Purpose (§ 1502.1)

CEQ proposes to divide § 1502.1 into paragraphs (a), (b), and (c) to enhance readability and amend the text in the section to restore the approach taken in the 1978 regulations regarding the purpose of EISs as they relate to NEPA.

In paragraph (a), CEQ proposes to restore language from the 1978 regulations clarifying that one purpose of an EIS is to serve as an action-forcing device for implementing the policies set out in section 101 of NEPA by ensuring agencies consider the environmental effects of their action in decision making. Congress did not enact NEPA to create procedure for procedure's sake; NEPA's procedures serve the substantive policies and goals Congress established and restoring the action-forcing language would clarify how EISs serve this broader function. This proposed change is consistent with the proposed edits in § 1500.1. *See* section II.B.1.

In paragraph (b), CEQ proposes minor edits for clarity and consistency with other changes proposed throughout the regulations. CEQ proposes to change ''It'' to ''Environmental impact statements'' to improve readability in light of the proposal to add paragraphs to the section. CEQ also proposes to change ''significant'' to ''important'' before ''environmental issues'' and insert ''reasonable'' before ''alternatives'' for consistency with similar phrasing throughout the regulations. In paragraph (c), CEQ proposes to restore the 1978 language clarifying that an EIS is more than a disclosure document and that agencies must use EISs concurrently with other relevant information to make informed decisions. CEQ considers this language to provide important direction to agencies to ensure that EISs inform planning and decision making and do not serve as a perfunctory check-the-box exercise.

2. Implementation (§ 1502.2)

CEQ proposes minor modifications in § 1502.2. First, CEQ proposes to restore from the 1978 regulations the introductory paragraph directing agencies to prepare EISs to meet the purpose established in § 1502.1. Upon reconsideration, CEQ is proposing to restore this language that was removed as unnecessary by the 2020 rule to provide clarity on the purpose of this section and improve readability.

Next, in paragraph (b) CEQ proposes to replace the word ''significant'' with ''important'' and add reference to an environmental assessment for clarity and consistency. In paragraph (c), CEQ proposes to change ''analytic'' to ''analytical,'' and ''project size'' to ''the scope and complexity of the action'' since this provision is applicable to more than projects, and the length of an EIS should be proportional to the scope and complexity of the action analyzed in the document.

CEQ proposes to delete ''as interpreted in'' before ''the regulations in this subchapter'' in paragraph (d), for the reasons discussed above for making a similar change in section II.B.5. CEQ is concerned that this phrase may inappropriately constrain agencies whose agency NEPA procedures go beyond the CEQ regulations. Under the proposal, EISs must state how alternatives and decisions will or will not achieve the requirements of NEPA, the CEQ regulations, and other environmental laws and policies. Finally, CEQ proposes to delete the word ''final'' in paragraph (f) because there is no distinction between a decision and final decision and for consistency with use of ''decision'' elsewhere in the regulations.

3. Scoping (§ 1502.4)

As discussed in section II.C.7 on § 1501.9, ''Public and governmental engagement,'' and § 1501.11, ''Programmatic review and tiering,'' CEQ proposes to revise § 1502.4 by retitling it ''Scoping'' and moving provisions from the current 40 CFR 1501.9 to this section. This proposal would move the requirements of scoping for EISs to part 1502, which addresses the requirements of EISs, while moving requirements for determining the appropriate level of NEPA review applicable to all environmental reviews to § 1501.3(b). CEQ also proposes to revise the provisions moved from the current 40 CFR 1501.9 to align scoping with related changes made on public engagement in § 1501.9 and to add requirements focused on increasing efficiency in the EIS scoping process.

CEQ has heard from multiple Federal agencies that there is uncertainty over the differences between the scoping process required for EISs and other public involvement or engagement requirements for NEPA reviews more generally. By proposing the revised§ 1501.9 on public and governmental engagement and moving the scoping provisions to § 1502.4, CEQ is emphasizing the importance of public engagement in the NEPA process generally, clarifying what requirements are unique to EISs, and clarifying what requirements and best practices agencies should consider regardless of the level of NEPA review.

As noted in sections II.C.2 and II.C.9, with the revision of this section to address scoping, CEQ proposes to move the existing provisions of 40 CFR 1502.4, ''Major Federal actions requiring the preparation of environmental impact statements'' to §§ 1501.3 and 1501.11.

CEQ proposes to move 40 CFR 1501.9(a), outlining the general purpose of scoping, to § 1502.4(a) and proposes to change the words ''significant'' and ''non-significant'' to ''important'' and ''unimportant,'' respectively, to align with CEQ's proposed change to only use the word ''significant'' when describing effects. CEQ intends this to be a clarifying, non-substantive change. CEQ proposes to move 40 CFR 1501.9(c) on scoping outreach to paragraph (b) and add a sentence requiring agencies to facilitate notification to persons and agencies who may be interested or affected by an agency's proposed action, consistent with the public engagement requirements in proposed § 1501.9. CEQ proposes to move 40 CFR 1501.9(b) on cooperating and participating agencies to paragraph (c) and retitle it ''Inviting participation'' to better reflect that the paragraph covers cooperating and participating agencies as well as proponents of the action and other likely affected or interested persons. CEQ notes that agencies invited to serve as cooperating or participating agencies should respond in a timely manner to facilitate the inclusion in the NOI any information that these agencies may need as part of the scoping process.

CEQ proposes to move 40 CFR 1501.9(f) and (f)(1) through (f)(5) on additional scoping responsibilities to paragraph (d) and (d)(1) though (d)(5), respectively. Within this list, CEQ proposes modifications to paragraph (d)(1) to change ''significant'' to ''important'' to align with changes in paragraph (a) and the use of ''significant'' throughout the

[69] *See* 2023 GHG Guidance, *supra* note 9.

regulations, which CEQ intends to be a clarifying, non-substantive change.

CEQ proposes to move the requirements for an NOI from 40 CFR 1501.9(d) and (d)(1) through (d)(8) to § 1502.4(e) and (e)(1) through (e)(8), respectively. CEQ proposes to delete the reference to 40 CFR 1507.3(f)(3) because CEQ is proposing to remove that provision from the regulations, as discussed in section II.I.2. CEQ proposes to revise the language in paragraph (e)(7) for consistency with section 107(c) requiring the NOI to include a request for public comment on alternatives or impacts and on relevant information, studies, or analyses, delete the cross reference to § 1502.17 because CEQ proposes to broaden the language in § 1502.17. Further, this cross reference would no longer be necessary since CEQ proposes to remove the exhaustion process in 40 CFR 1500.3, which relies, in part, on this provision as the first step in that process. Additionally, the purpose of scoping is to receive input from the public on the proposed action and alternatives as well as other information relevant to consideration of the proposed action. CEQ considers the language in this paragraph to be redundant to the other required information in paragraph (e).

To this list of NOI requirements, CEQ proposes to add paragraph (e)(9) to require the lead agency to list any cooperating and participating agencies that have been identified at the time of the NOI, as well as any information those agencies require to facilitate their decisions or authorizations related to the EIS. CEQ proposes to add this requirement to ensure that lead and cooperating agencies are communicating about any unique statutory or regulatory requirements of each agency so that the necessary information is included in the initial NOI and does not require re-issuance of a second NOI by the cooperating or participating agency. For example, the U.S. Forest Service's regulations regarding administrative review require the responsible official to disclose during the NEPA scoping process that a proposed project or activity or proposed plan, plan amendment, or plan revision is subject to one of its administrative review regulations. 36 CFR 218.7(a), 219.52(a). When the Forest Service acts as a cooperating agency and the lead agency does not include the necessary information in the NOI, the Forest Service then must issue its own NOI, which can add additional time in the NEPA process.

CEQ also proposes to add paragraph (e)(10) to require that the NOI include a unique identification number for tracking purposes that would be carried forward to all other documents related to the action such as the draft and final EISs and ROD. Identification numbers can help both the public and agencies track the progress of an EIS for a specific action as it moves through the NEPA process. CEQ has similarly proposed to require agencies to use tracking numbers for environmental assessments in § 1501.5. *See* section II.C.4.

CEQ proposes to move and edit the second sentence regarding supplemental notices in 40 CFR 1507.3(f)(3) to paragraph (f), ''Notices of withdrawal or cancellation,'' to require that an agency publish in the **Federal Register** a notice of withdrawal of the NOI or a supplemental notice to inform the public that it is no longer considering a proposed action and, therefore, discontinuing preparation of an EIS. Agencies should publish such notices if they withdraw, cancel, or otherwise cease the consideration of a proposed action before completing a final EIS. CEQ proposes this requirement to codify common agency practice and to increase transparency to the public. Such a notice does not need to be lengthy, but should clearly reference the original NOI, name of the project in the original notice, unique identification number, and who to contact for additional information.[70] Finally, CEQ proposes to move 40 CFR 1501.9(g) on NOI revisions to § 1502.4(g), updating the paragraph references and changing ''significant'' to ''important'' and ''impacts'' to ''effects,'' which CEQ intends to be a clarifying, non-substantive edit. These edits would align the text with the proposed changes to § 1502.9(d)(1)(ii).

4. Timing (§ 1502.5)

CEQ proposes to make three clarifying amendments to § 1502.5. First, in paragraph (a), CEQ proposes to add ''*e.g.,*'' in the parenthetical ''(go/no-go).'' CEQ proposes this amendment in response to agency feedback during the development of the proposed rule to clarify that the feasibility analysis and the ''go/no-go'' stage may not occur at the same point in time and may differ depending on what is included in the feasibility analysis and how the agency has structured that analysis. This change would be consistent with the longstanding practice that agencies have discretion to decide the appropriate time to begin the NEPA analysis, but also that agencies should integrate the NEPA process and other planning or authorization processes early. *See* § 1501.2(a).

Second, CEQ proposes to add ''complete'' in the first sentence of paragraph (b) to clarify that agencies must begin preparing an EIS after receiving a complete application, though agencies can elect to begin the process earlier if they choose to do so. CEQ also proposes to add ''together and'' in the second sentence of paragraph (b) to clarify further that agencies should work ''together and with'' potential applicants and other entities before receiving the application. Based on CEQ's experience, early conversations and coordination among Federal agencies, the applicant, and other interested entities can improve efficiencies in the NEPA process and ultimately lead to better environmental outcomes. Additionally, similar to the proposed change to paragraph (a), this proposed change is consistent with other directions in the regulations to integrate the NEPA process and other processes early. *See* §§ 1500.5(h), (i), 1501.2(a).

5. Page Limits (§ 1502.7)

CEQ proposes to amend § 1502.7, to align the text with section 107(e) of NEPA, which sets page limits for EISs at 150 pages or 300 pages for proposals of extraordinary complexity, not including citations or appendices. CEQ proposes to remove the requirement for the senior agency official of the lead agency to approve longer documents for consistency with the statute, which does not provide a mechanism to approve longer documents.

CEQ strongly encourages agencies to prepare concise EISs that are both comprehensive and understandable to the decision maker and the public. Agencies should consider establishing within their procedures mechanisms to do so that will be most effective for their programs and activities. Such mechanisms might include placing technical analyses in appendices and summarizing them in plain language in the EIS; making use of visual aids, which are excluded from the definition of ''page,'' including sample images, maps, drawings, charts, graphs, and tables; and using insets, colors, and highlights to create visually interesting ways to draw attention to key information and conclusions. Agencies should consider making EISs and technical appendices machine readable, where possible and feasible, to facilitate data sharing and reuse in future

[70] Examples of NOI Withdrawals: Powell Ranger District; Utah; Powell Travel Management Project; Withdrawal of Notice of Intent to Prepare an Environmental Impact Statement, 87 FR 1109 (Jan. 10, 2022); Withdrawal of the Notice of Intent to Prepare an Environmental Impact Statement for the Carpinteria Shoreline, a Feasibility Study in the City of Carpinteria, Santa Barbara County, CA, 86 FR 41028 (July 30, 2021).

analyses. CEQ invites comment on whether CEQ should modify the regulations to appropriately encourage agencies to do so.

6. Writing; and Draft, Final, and Supplemental Statements (§§ 1502.8 and 1502.9)

CEQ proposes minor edits to § 1502.8 to make the text consistent with modifications proposed in § 1502.12 regarding visual aids or charts.

CEQ proposes to delete ''as interpreted'' before ''in the regulations in this subchapter'' in § 1502.9(b), as section II.B.5 explains. CEQ also proposes to clarify that it is the agency preparing a draft EIS that determines a draft statement requires supplementation to inform its decision-making process.

In § 1502.9(c), CEQ proposes to clarify that a final EIS should ''consider and respond'' to comments rather than just ''address'' them, restoring language from the 1978 regulations and aligning the language with text at § 1503.4(a) regarding consideration of comments. The 2020 rule did not explain the change to ''address,'' [71] and CEQ is concerned that it could be read as weakening the standard for responding to comments within § 1502.9 and in § 1503.4. In paragraphs (d)(1)(ii) and (d)(4), CEQ proposes to replace the word ''significant'' with ''important'' and ''impacts'' with ''effects'' (except where ''impact'' is used as part of the term FONSI) for consistency, as discussed in section II.A. In paragraph (d)(1)(ii), CEQ also proposes to add ''substantial or'' before ''important new circumstances or information,'' for consistency with its use section 108(1) of NEPA, which confirms that an agency may rely on the analysis in an existing programmatic environmental document for five years without having to supplement or reevaluate the analysis, provided no substantial new circumstances or information exist. CEQ invites comment on whether it should revise the language in paragraphs (d)(1)(i) and (d)(1)(ii) to more specifically identify situations where supplementation is required.

CEQ proposes to redesignate 40 CFR 1502.9(d)(4) as § 1502.9(e), title it ''Reevaluation,'' making this a standalone paragraph rather than a paragraph of supplemental EISs to clarify that reevaluation is a separate tool to document when supplementation is not required. CEQ proposes to add in paragraph (e) that agencies may ''reevaluate'' an EIS in part to determine ''that the underlying assumptions of the analysis remains valid.'' That language is generally consistent with section 108(2) of NEPA's rule that an agency may rely on programmatic documents that are more than five years old if it reevaluates the underlying analysis. However, while section 108(2) requires reevaluation for programmatic documents more than five years old, CEQ proposes to leave agencies discretion over whether and when to reevaluate non-programmatic documents.

7. Recommended Format and Cover (§§ 1502.10 and 1502.11)

CEQ proposes to revise the recommended format of an EIS. CEQ proposes to include the summary of scoping information required by § 1502.17 and the list of preparers required by § 1502.18 in appendices, rather than the main body of the EIS. Therefore, CEQ proposes to remove 40 CFR 1502.10(a)(7) through (9), and add a new paragraph (a)(7) requiring appendices including the scoping summary and list of preparers.

CEQ proposes to clarify in § 1502.11(a) that the list of ''responsible agencies'' on an EIS cover are the lead, joint lead, and any cooperating agencies. Consistent with the proposed change in § 1502.4(e)(10), CEQ proposes to amend paragraph (g) to require the cover to include the identification number identified in the NOI to make clear the relationships of documents to one another and help the public and decision makers easily track the progress of the EIS as it moves through the NEPA process and to facilitate digitization and analysis.

CEQ proposes to strike the existing requirement in 40 CFR 1502.11(g) to include on the cover of the final EIS the estimated preparation cost, a change that multiple Federal agencies requested during development of this proposed rule. The 2020 rule stated that including estimated total costs would be helpful for tracking such costs, and that agencies could develop their own methodologies for tracking EIS preparation costs in their agency NEPA procedures.[72] However, Federal agency commenters stated that agencies typically do not estimate total costs, that they are difficult to monitor especially when project sponsors and contractors are bearing some of the cost, that the methodology for estimating costs is inconsistent across agencies, and that providing these estimates would be burdensome. At least one agency commenter noted that agencies inconsistently implemented a similar requirement in E.O. 13807, which undermined the utility of the estimates, that tracking costs added a significant new burden on staff, and that it was not clear whether tracking such costs provided useful information for agencies or the public.

CEQ does not consider EIS costs to be germane to the purpose of an EIS. Requiring that they be included on the cover could incorrectly lead the public and decision makers to believe that those costs relate to the proposed action addressed in the EIS. In general, the purpose of the cover is to indicate the subject matter of the document and provide the public with an agency point of contact, provide a short abstract of the EIS, and indicate the date by which the public must submit comments. Further, CEQ is concerned that requiring agencies to calculate the costs may unnecessarily add time to the EIS preparation process, particularly where aspects of an environmental review serve multiple purposes and allocating costs to NEPA compliance and other obligations may be complicated.

CEQ recognizes the value in gathering information on overall costs, trends in costs, and approaches that can reduce costs, as this can provide a full picture of how and whether agencies are effectively using their resources, including to conduct environmental reviews. Each agency should track and monitor these costs through their own procedures and mechanisms and consult with CEQ about any lessons learned to inform CEQ's ongoing evaluation of the efficiency and effectiveness of the NEPA process. CEQ does not consider requiring in the NEPA regulations that agencies publish costs on the cover of EISs to be the appropriate mechanism to develop that information.

8. Summary (§ 1502.12)

CEQ proposes modifications to § 1502.12 to clarify the purpose of the summary and update what elements agencies should include in the summary with a goal of creating summaries that are more useful to the public and agencies. The summary serves to provide the public and decision makers with a clear, high-level overview of the proposed action and alternatives, the significant effects, and other critical information in the EIS.

CEQ proposes a few changes to the second sentence in § 1502.12. First, CEQ proposes to replace the word ''stress'' with ''include'' in describing the contents of the summary to clarify that an adequate and accurate summary may include more than what is listed in § 1502.12. Next, CEQ proposes to clarify that the summary should summarize

[71] *See* 2020 Final Rule, *supra* note 36.

[72] *Id.*

disputed issues, any issues to be resolved, and key differences among alternatives. CEQ proposes this change to provide the public and decision makers with a more complete picture of the disputed issues rather than focusing on ''areas of'' disputed issues and to facilitate informed decision making and transparency. These edits are also consistent with § 1502.14(b), which requires agencies to discuss alternatives in detail. Summarizing the key differences of alternatives could enhance the public's and decision makers' understandings of the relative trade-offs of the alternatives considered in detail.

CEQ also proposes to add language to the second sentence to require that the summary identify the environmentally preferable alternative or alternatives. Adding the environmentally preferable alternative to the summary would enhance the public's and decision makers' understandings of the alternative or alternatives that will best promote the national environmental policy as expressed in section 101 of NEPA by providing a summary of that alternative early on in the document.

CEQ proposes to add a fourth sentence to § 1502.12 to make summaries easier to read and understand by requiring agencies to write the summary in plain language and encouraging use of visual aids and charts. Existing regulatory text already requires agencies to write environmental documents in plain language as a means to preparing readable, concise, and informative documents. *See, e.g.,* §§ 1500.4 and 1502.8. Agencies commonly use visual aids, such as graphics, maps, and pictures, throughout their environmental documents.

Finally, similar to other changes proposed regarding page limits, CEQ proposes to allow agencies flexibility in the length of a summary. In the existing text, summaries are limited to 15 pages. CEQ proposes instead to encourage summaries to not exceed 15 pages. Although summaries should be brief, CEQ acknowledges with this proposed change that some proposed actions are more complex and may require additional pages.

9. Purpose and Need; Alternatives Including the Proposed Action (§§ 1502.13 and 1502.14)

CEQ proposes to revise § 1502.13 to align the language with the text of section 107(d) of NEPA requiring an EIS to include statement that briefly summarizes the underlying purpose and need for the proposed agency action.

CEQ proposes revisions to § 1502.14 to promote the rigorous analysis and consideration of alternatives, consistent with the longstanding principle that agencies take a ''hard look'' at their actions. To that end, CEQ proposes to reintroduce much of the 1978 text to § 1502.14 that the 2020 rule removed and modernize it to ensure agency decision makers are well-informed. Many commenters on the Phase 1 rule requested CEQ revise this provision to revert to the 1978 language or revise it to ensure agencies fully explore the reasonable alternatives to their proposed actions.[73]

CEQ proposes to revise the introductory paragraph of § 1502.14 to reinstate the language from the 1978 regulations that the alternatives analysis ''is the heart of the environmental impact statement.'' While the 2020 rule described this clause as ''colloquial language'' to justify its removal,[74] CEQ now considers this to be an integral policy statement necessary to emphasize the importance of the alternatives analyses to allow decision makers to assess a reasonable range of possible approaches to the matters before them and notes that numerous court decisions quoted this language from the 1978 regulations in stressing the importance of the alternatives analysis. *See, e.g., Wyoming* v. *U.S. Dep't of Agric.,* 661 F.3d 1209, 1243 (10th Cir. 2011). Numerous commenters on the 2020 rule and the 2022 Phase 1 rule supported inclusion of this language.[75]

CEQ proposes a clarifying edit in the introductory paragraph, replacing ''present'' the environmental effects with ''identify'' the ''reasonably foreseeable'' environmental effects consistent with § 1500.2(e) and section 102(2)(C)(i) of NEPA. Finally, in the introductory paragraph, CEQ proposes to state that the alternatives analysis should sharply define issues for the decision maker and the public and provide a clear basis for choice in the options. CEQ proposes reintroducing this language from the 1978 regulations because it provides an important policy statement, concisely explaining the end goals for the alternatives analysis.

CEQ proposes in paragraph (a) to restore the clause that agencies must ''rigorously explore and objectively'' evaluate reasonable alternatives at the beginning of the first sentence. CEQ proposes to reinsert this language because it provides a standard for how agencies should analyze alternatives. CEQ proposes to add two additional sentences to paragraph (a). One statement would clarify that agencies need not consider every conceivable alternative to a proposed action but rather must consider a reasonable range of alternatives that fosters informed decision making. CEQ proposes to add this sentence to replace the statement in the current 40 CFR 1502.14(f) requiring agencies to limit their consideration to a reasonable number of alternatives, which CEQ proposes to strike. This proposed language is consistent with longstanding CEQ guidance[76] and would reinforce that the alternative analysis is not boundless; the key is to provide the decision maker with reasonable options to ensure informed decision making. To that end, CEQ also proposes in paragraph (a) to clarify that agencies have the discretion to consider reasonable alternatives not within their jurisdiction, but NEPA and the CEQ regulations generally do not require them to do so. Such alternatives may be relevant, for instance, when agencies are considering program-level decisions[77] or anticipate funding for a project not yet authorized by Congress.[78] CEQ anticipates that such consideration would be a relatively infrequent occurrence and notes that such alternatives would still need to be technically and economically feasible and meet the purpose and need for the proposed action, consistent with the definition of ''reasonable alternatives.'' CEQ considers adding this language to paragraph (a) to improve the consistency of the regulations with the ''hard look'' principle of NEPA.

Some commenters—both on the 2020 rule and the Phase 1 rule—supported the removal of the 1978 regulations' requirement to consider alternatives outside the jurisdiction of the lead agency, contending that such alternatives are inherently infeasible.[79] However, many commenters on the

[73] *See* Phase 1 Response to Comments, *supra* note 48, at 162.

[74] 2020 Final Rule, *supra* note 36, at 43330.

[75] *See, e.g.,* 2020 Response to Comments, *supra* note 63, at 274; Phase 1 Response to Comments, *supra* note 48, at 55.

[76] Forty Questions, *supra* note 4.

[77] *See, e.g.,* Fed. R.R. Admin., Final Program Environmental Impact Report/Environmental Impact Statement (EIR/EIS) for the proposed California High-Speed Train System (2005), *https://hsr.ca.gov/programs/environmental-planning/program-eir-eis-documents-for-the-statewide-high-speed-rail-system-tier-1/final-program-environmental-impact-report-environmental-impact-statement-eir-eis-for-the-proposed-california-high-speed-train-system-2005/.*

[78] *See, e.g.,* U.S. Army Corps of Eng'rs, *Final Environmental Impact Statement for Savannah Harbor Expansion Project* (rev. July 2012), *https://www.sas.usace.army.mil/Missions/Civil-Works/Savannah-Harbor-Expansion/Final-Environmental-Impact-Statement/.*

[79] 2020 Final Rule, *supra* note 36, at 43330–31; 2020 Response to Comments, *supra* note 63, at 45, 57.

Phase 1 rule supported the reintroduction of this language.[80] CEQ's proposal is intended to strike a balance; the proposal would not require agencies to consider alternatives outside their jurisdiction or preclude agencies from doing so. Further, it would retain the direction that the agency need only consider reasonable alternatives.

CEQ proposes to replace paragraph (f) with a requirement to identify the environmentally preferable alternative. In addition to the proposed definition of environmentally preferable alternative in § 1508.1(*l*), this provision would describe elements that the environmentally preferable alternative may generally include. The list uses ''or'' to make clear that the environmentally preferable alternative need not include each delineated element and recognizes that identifying the environmentally preferable alternative may entail making tradeoffs in some cases. This approach would provide agencies flexibility to rely on their discretion and expertise to strike an appropriate balance in identifying the environmentally preferable alternative. Finally, paragraph (f) would clarify that the environmentally preferable alternative may be the proposed action, no action alternative, or a reasonable alternative. Agencies may identify more than one environmentally preferable alternative as they deem appropriate.

The CEQ regulations, at 40 CFR 1505.2, always have required agencies to identify the environmentally preferable alternative in a ROD. CEQ's proposal would provide more context for what this alternative entails, improving consistency and furthering NEPA's goal of ensuring that agencies make informed decisions regarding actions that impact the environment. Additionally, requiring that the draft and final EIS identify the environmentally preferable alternative would provide more transparency to the public as to the agency's decision-making process at an earlier stage, as well as an opportunity to comment on it before the agency makes its decision.

10. Affected Environment (§ 1502.15)

CEQ proposes revisions to § 1502.15 to emphasize the use of high-quality information, including best available science and data; clarify considerations of reasonably foreseeable environmental trends; and emphasize efficiency and concise documents. CEQ also proposes to divide § 1502.15 into paragraphs (a), (b), and (c) to improve readability.

CEQ proposes to discuss data in a new paragraph (b), which would encourage agencies to use high-quality information, including best available science and data, in recognition that these should inform all agency decisions. This paragraph would articulate clearly NEPA's statutory mandate that science inform agencies' decisions as part of a systematic, interdisciplinary approach. *See* 42 U.S.C. 4332(2)(A). In addition, the paragraph would clarify that this information should inform agencies' consideration of ''reasonably foreseeable environmental trends,'' noting explicitly that this includes anticipated climate-related changes to the environment.

CEQ proposes this language to clarify that agencies should consider reasonably foreseeable future climate conditions on affected areas rather than merely describing general climate change trends at the global or national level. In line with scientific projections, accurate baseline assessment of the affected environment over an action's lifetime should incorporate forward-looking climate projections rather than relying on historical data alone. CEQ also proposes language in paragraph (b) to connect the description of baseline environmental conditions and reasonably foreseeable trends to an agency's analysis of environmental consequences and mitigation measures.

CEQ proposes to move the second and third through fifth sentences of 40 CFR 1502.15 to new paragraph (c). CEQ also proposes minor revisions to the relocated language and a new sentence to provide that agencies may combine the affected environment and environmental consequences sections in an EIS, which should be no longer than necessary to understand the relevant affected environment and the effects of the alternatives.

11. Environmental Consequences (§ 1502.16)

CEQ proposes several changes to § 1502.16 to clarify priorities and methods of analysis and make updates to ensure that agencies integrate climate change and environmental justice considerations into the analysis of environmental effects.

CEQ proposes in paragraph (a)(1) to modify the sentence requiring agencies to base the comparison of the proposed action and reasonable alternatives on the discussion of effects to add ''reasonably foreseeable'' before ''environmental effects'' for consistency with the text of section 102(2)(C)(i) of NEPA and to focus the comparison of the proposed action and reasonable alternatives on the ''significant or important effects'' to emphasize that agencies' analyses of effects should be proportional to the significance of the effects. The FRA's amendments to NEPA codified the longstanding principle from the 1978 regulations and long recognized by the courts that effects must be reasonably foreseeable. Consistent with this provision, agencies should identify the effects they deem significant whenever possible to inform the public and decision makers. Finally, CEQ proposes adding a new sentence to the end of paragraph (a)(1) clarifying the proper role of the no action alternative to ensure that the comparative analysis is not distorted by selecting a different alternative (for example, the preferred alternative) as the baseline against which all other alternatives are measured. In formulating the no action alternative, agencies should make reasonable assumptions. CEQ invites comment on whether it should include additional direction or guidance regarding the no action alternative in the final rule.

Next, CEQ proposes to add ''reasonably foreseeable'' in paragraph (a)(1) before ''environmental effects'' for consistency with section 102(2)(C)(i) of NEPA and in paragraph (a)(2) before ''adverse environmental effects'' for consistency with section 102(2)(C)(ii) of NEPA. CEQ proposes to add a new paragraph (a)(3) requiring an analysis of effects of the no action alternative, including any adverse environmental effects consistent with section 102(2)(C)(iii) of NEPA, which requires an analysis of any negative environmental impacts of not implementing the proposed action in the case of a no action alternative. CEQ interprets ''negative'' to have the same meaning as the term ''adverse.'' For example, an environmental restoration project that helps mitigate the effects of climate change and restores habitat could have adverse effects if it were not implemented or the construction of a commuter transit line could have adverse effects from persistent traffic congestion, air pollution, and related effects to environmental justice communities if it were not implemented. To accommodate this additional paragraph, CEQ proposes to redesignate 40 CFR 1502.15(a)(3) through (a)(5) as paragraphs (a)(4) through (a)(6) accordingly. In paragraph (a)(5), CEQ proposes to insert ''Federal'' before ''resources'' for consistency with section 102(2)(C)(v) of NEPA.

Then, CEQ proposes to add reference to two specific elements and revise the reference to an existing element that agencies must include in the analysis of environmental consequences, all related

[80] Phase 1 Response to Comments, *supra* note 48, at 162.

to climate change. First, CEQ proposes to revise paragraph (a)(6) to broaden it from land use plans to plans generally and clarify that this element includes plans and policies addressing climate change. Second, CEQ proposes to add a new paragraph (a)(7) to clarify that the discussion of environmental consequences in an EIS must include any reasonably foreseeable climate change-related effects, including effects of climate change on the proposed action and alternatives (which may in turn alter the effects of the proposed action and alternatives). CEQ would then redesignate the paragraphs at 40 CFR 1502.16(a)(6) and(a)(7) as paragraphs (a)(8) and (a)(9), respectively. Third, CEQ proposes to add a new paragraph (a)(10), which would require agencies to address any risk reduction, resiliency, or adaptation measures included in the proposed action and alternatives. This would ensure agencies consider resiliency to the risks associated with a changing climate, including wildfire risk, extreme heat and other extreme weather events, drought, flood risk, loss of historic and cultural resources, and food scarcity. This analysis would further NEPA's mandate that agencies use ''the environmental design arts'' in decision making and consider the relationship between the ''uses'' of the environment ''and the maintenance and enhancement of long-term productivity.'' 42 U.S.C. 4332(2)(A) and (2)(C)(iv). It also would help achieve NEPA's goals of protecting the environment across generations, preserving important cultural and other resources, and attaining ''the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.'' 42 U.S.C. 4331(b)(3).

These proposed revisions would clarify that agencies must address both effects of the proposed action and alternatives on climate change, and the resiliency of the proposed action and alternatives in light of climate change.[81] These proposed revisions are consistent with what NEPA has long required: using science to make informed decisions. This proposal is also consistent with NEPA's specific requirement to study the effects of the Federal action because effects on the Federal action due to climate change may in turn alter the effects that the project has on its environment. These proposed revisions also align well with the definition of effects to encompass reasonably foreseeable indirect and cumulative effects, which are integral to NEPA analyses.

To accommodate the new paragraph (a)(10), CEQ proposes to redesignate 40 CFR 1502.16(a)(8) through (a)(10) as paragraphs (a)(11) through (a)(13), respectively. Finally, CEQ proposes to add paragraph (a)(14) to provide that agencies must discuss the potential for disproportionate and adverse health and environmental effects on communities with environmental justice concerns. The addition of this paragraph would clarify that EISs generally must include an environmental justice analysis to ensure that agency actions do not unintentionally impose disproportionate and adverse effects on these communities.

Finally, CEQ proposes to strike ''and give appropriate consideration to'' from paragraph (b). CEQ proposes this revision to remove unnecessary language that could be read to require the decision maker to make consideration of such effects a higher priority than other effects listed in this section.

12. Summary of Scoping Information (§ 1502.17)

CEQ proposes to revise § 1502.17 and retitle it ''Summary of scoping information'' to more accurately reflect the proposed content of this section and align it with the common practice of what many agencies produce via scoping reports. CEQ proposes other changes in this section to simplify and remove unnecessary or redundant text and clarify requirements.

CEQ proposes to revise paragraph (a) to require agencies to include a summary of the information they receive from commenters during the scoping process in draft EISs consistent with the proposed revisions to §§ 1500.3, 1501.9, and 1502.4. CEQ proposes to replace ''State, Tribal, and local governments and other public commenters'' with ''commenters'' because this phrase is all encompassing. CEQ also proposes to clarify that a draft EIS should include a summary of information, including alternative and analyses, that commenters submitted during scoping. This change provides agencies flexibility to develop a broader summary of information received during scoping. While agencies should still summarize alternatives and analyses, this provision would not require them to provide a specific summary of every individual alternative, piece of information, or analysis commenters submit during scoping.

CEQ proposes to redesignate paragraph (a)(1) as paragraph (b) and modify it to clarify that agencies can either append to the draft EIS or otherwise make publicly available comments received during scoping. This modification clarifies that the requirements of this paragraph can be met through means other than an appendix, such as a scoping report, which is common practice for some Federal agencies. CEQ proposes a conforming edit in paragraph (d) of § 1502.19, ''Appendix,'' for consistency with this language.

Finally, CEQ proposes to delete the current 40 CFR 1502.17(a)(2) and (b) because the requirements of these paragraphs are redundant to the requirements in part 1503 for Federal agencies to invite comment on draft EISs in their entirety and review and respond to public comments.

13. Incomplete or Unavailable Information (§ 1502.21)

CEQ proposes one revision to paragraph (b) of § 1502.21 to strike ''but available,'' which addresses situations where an agency encounters incomplete or unavailable information during its evaluation of a proposed action's reasonably foreseeable significant adverse effects. CEQ proposes to strike ''but available,'' a phrase added by the 2020 rule, to clarify that agencies must obtain information relevant to reasonably foreseeable significant adverse effects that is essential to a reasoned choice between alternatives where the overall costs of doing so are not unreasonable, and the means of obtaining that information are known. This qualifier, which CEQ proposes to remove, could be read to significantly narrow agencies' obligations to obtain additional information even when it is easily attainable and the costs are reasonable. CEQ has reconsidered this change and now considers it vital to the NEPA process for agencies to undertake studies and analyses where necessary rather than relying solely on available information where the costs of obtaining the relevant information are not unreasonable.

Agency feedback received during the development of this proposed rule supports this change. Agency NEPA experts indicated that this qualifier could be read to say that agencies do not need to collect additional information that could and should otherwise inform the public and decision makers. Removing this phrase also would be

[81] Such analysis is not new and CEQ has issued guidance consistent with these proposed provisions for nearly a decade. *See generally* CEQ, Final Guidance for Federal Departments and Agencies on Consideration of Greenhouse Gas Emissions and the Effects of Climate Change in National Environmental Policy Act Reviews, 81 FR 51866 (Aug. 8, 2016), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/nepa_final_ghg_guidance.pdf,* and 2023 GHG Guidance, *supra* note 9.

consistent with other provisions in the regulations emphasizing the importance of relying on high-quality and accurate information in implementing NEPA. *See, e.g.,* § 1500.1(b).

14. Methodology and Scientific Accuracy (§ 1502.23)

CEQ proposes changes to § 1502.23 to promote use of high-quality information, such as best available science and data; require agencies to explain assumptions; and, where appropriate, incorporate projections, including climate change-related projections, in the evaluation of reasonably foreseeable effects. CEQ proposes to separate existing 40 CFR 1502.23 into paragraphs (a) and (b), with some modification, and add a new paragraph (c). The proposed changes to this section would provide additional guidance on how Federal agencies can meet NEPA's statutory requirement to ''study, develop, and describe appropriate alternatives to recommended courses of action in any proposal'' as set forth in section 102(2)(H) of NEPA.

In paragraph (a), CEQ proposes to reinstate the term high-quality information, as used in the 1978 regulations, and clarify that such information includes best available science and reliable data, models, and resources. Also, CEQ proposes clarifying edits, including moving the word ''existing'' in the second sentence of paragraph (a) to the end of the sentence and adding reference to sources and materials. CEQ proposes these changes to clarify that while agencies must use reliable data and resources, which can include existing data and resources, they are not limited to use of existing materials. Public commenters on the 2020 rule and Federal agency experts who provided input on this proposed rule raised concerns that the 2020 language could limit agencies to ''existing'' resources and preclude agencies from undertaking site surveys, conducting investigation, and performing other forms of data collection, which have long been standard practice when analyzing an action's potential environmental effects and may be necessary for agencies to understand particular effects.

For example, in the context of analyzing historical, cultural, or biological effects, survey work is often revisited and reassessed periodically, and an agency should not be required to rely on outdated data. While there are numerous reliable data sources for a variety of resources analyzed in NEPA documents, and the CEQ regulations encourage the use of existing information wherever possible, *see* § 1501.12, agencies should be permitted to exercise their good judgment in determining when new data and analyses are necessary. Indigenous Knowledge also can be a source of high-quality information.

CEQ proposes to add a new sentence at the end of paragraph (a) encouraging agencies to explain their assumptions and any limitations of their models and methods. CEQ proposes this addition to support this section's overall purpose of ensuring the integrity of the discussions and analyses in environmental documents. Additionally, this would codify typical agency practice to explain relevant assumptions or limitations of the information in environmental documents.

CEQ proposes to strike the statement that agencies are not required to undertake new research to inform their analyses consistent with the changes to paragraph (a). As noted in this section, it is common practice for agencies, when necessary or appropriate, to engage in additional research and create new data based on an action's particular circumstances (such as the affected environment) when analyzing proposed actions under NEPA. Further, by simply striking the sentence added in 2020, CEQ is not proposing to add an across-the-board requirement that agencies must undertake new research in all cases.

Finally, CEQ proposes to add a new paragraph (c), which would require agencies to use projections when evaluating reasonably foreseeable effects, including climate change-related effects, where appropriate. CEQ also proposes to clarify that such projections may employ mathematical or other models that project a range of possible future outcomes, so long as agencies disclose the relevant assumptions or limitations. This addition is consistent with the amendments proposed in paragraphs (a) and (b). Based on existing agency practice and academic literature on climate science, agencies can and do use reliable projections to analyze reasonably foreseeable climate change-related effects. Where available and appropriate, agencies also can use or rely on projections that are scaled to a more targeted and localized geographic scope, such as land use projections, air emissions, and modeling, or to evaluate climate effects experienced locally in relation to the proposed action. When doing so, agencies should explain the basis for relying on those projections and their underlying assumptions. Climate projections can vary based on different factors and assumptions such as geography, location, and existing and future GHG emissions. For that reason, agencies can use models that analyze a range of possible future outcomes, but agencies must disclose the underlying relevant assumptions or limitations of those models.

CEQ expects that modeling techniques will continue to improve in the future, resulting in more precise climate projections. To be consistent with proposed changes with paragraph (a) in this section, as climate modeling techniques advance, agencies should rely on high-quality information when evaluating reasonably foreseeable climate change-related effects.

E. Proposed Revisions To Update Part 1503, Commenting on Environmental Impact Statements

CEQ is proposing substantive revisions to all sections of part 1503, except § 1503.2, Duty to comment. CEQ invites comments on whether it should make changes to this section or other changes to part 1503.

1. Inviting Comments and Requesting Information and Analyses (§ 1503.1)

CEQ proposes to delete 40 CFR 1503.1(a)(3) requiring agencies to invite comment specifically on the submitted alternatives, information, and analyses and the summary thereof for consistency with proposed changes to §§ 1500.3 and 1502.17. This requirement would be unnecessary with the removal of the exhaustion provision. It also is redundant as Federal agencies invite comment on all sections of draft EISs and therefore need not invite comment on one specific section of an EIS.

2. Specificity of Comments and Information (§ 1503.3)

CEQ proposes edits to § 1503.3 to clarify the expected level of detail in comments submitted by the public and other agencies to facilitate their consideration by agencies in the decision-making process. The proposal would remove or otherwise modify provisions that could inappropriately restrict public comments and place unnecessary burden on public commenters.

CEQ proposes to remove language from § 1503.3(a) added in the 2020 rule that requires comments to be as detailed as necessary to meaningfully participate and fully inform the agency of the commenter's position because this requirement could lead commenters to provide unnecessarily long comments that will impede efficiency. Paragraph (a) already requires comments to be ''as specific as possible,'' and the language CEQ proposes to remove could be read

to require commenters to provide detailed information that is not pertinent to the NEPA analysis about the commenter's position on the proposed action, the project proponent, the Federal agency, or other issues. For example, the text could be read to require a commenter to provide a detailed explanation of a moral objection to a proposed action or a personal interest in it if those inform the commenter's position on the project. The text also could imply that commenters must either be an expert on the subject matter or hire an expert to provide the necessary level of detail. The current text could be read to imply that commenters are under an obligation to collect or produce information necessary for agencies to fully evaluate issues raised in comments even if the commenters do not possess that information or the skills necessary to produce it. Some commenters on the 2020 rule raised this issue, expressing concerns that this language could be read to require the general public to demonstrate a level of sophistication and technical expertise not required historically under the CEQ regulations or consistent with the NEPA statute.[82] Commenters also expressed concern that the requirement would discourage or preclude laypersons or communities with environmental justice concerns from commenting.[83] Other commenters on the 2020 rule expressed concern that the changes would shift the responsibility of analysis from the agencies to the general public.[84] Finally, CEQ proposes to remove this language because the requirements that comments provide as much detail as necessary to ''meaningfully'' participate and ''fully inform'' the agency are vague and put the burden on the commenter to anticipate the appropriate level of detail to meet those standards.

CEQ also proposes to delete from paragraph (a) language describing the types of impacts that a comment should cover, including the reference to economic and employment impacts. CEQ proposes this deletion because this language imposes an inappropriate burden on commenters by indicating that comments need to explain why an issue matters for economic and employment purposes. NEPA requires agencies to analyze the potential effects on the human environment and does not require that these effects be specified in economic terms or related specifically to employment considerations. Therefore, it is inappropriate to single out these considerations for special treatment and unduly burdensome to expect commenters to address economic and employment impacts. The proposed revision would not have the effect of limiting commenters from addressing these issues but would avoid the implication that members of the public are welcome to comment only if they address those issues. CEQ proposes to delete the reference to ''other impacts affecting the quality of the human environment'' because it is unnecessary and duplicative of ''consideration of potential effects and alternatives.''

Finally, in paragraph (a), CEQ proposes changes to the last sentence to clarify that, only where possible, the public should include citations or proposed changes to the EIS or describe the data, sources, or methodologies that support the proposed changes in their comments. While such information is helpful to the agency whenever it is readily available, CEQ has concerns that this could be construed to place an unreasonable burden on commenters.

CEQ proposes to strike 40 CFR 1503.3(b) and redesignate 40 CFR 1503.3(c) through (d) as § 1503.3(b) and (c). CEQ proposes the deletion of paragraph (b) for consistency with proposed changes to § 1500.3's exhaustion requirement and corresponding changes to § 1502.17. The paragraph also is unrelated to the subject addressed in § 1503.3, which addresses the specificity of comments, rather than when commenters should file their comments. Further, agencies have long had the discretion to consider special or unique circumstances that may warrant consideration of comments outside those time periods. CEQ proposes to strike ''site-specific'' in paragraph (c) to clarify that cooperating agencies must identify additional information needed to address significant effects generally. This proposed change would enhance efficiency because it would ensure that cooperating agencies have the information they need to fully comment on EISs averting potential delay in the environmental review process.

Finally, CEQ proposes in paragraph (d) to strike the requirement for cooperating agencies to cite their statutory authority for recommending mitigation. This requirement is unnecessary since, at this stage, those agencies with jurisdiction by law have already established their legal authority to participate as cooperating agencies. CEQ also proposes in paragraph (d) to replace the reference to ''permit, license, or related requirements'' with ''authorizations'' because the definition of ''authorization'' in § 1508.1(c) is inclusive of those terms.

3. Response to Comments (§ 1503.4)

CEQ proposes to revise paragraph (a) to clarify that agencies must respond to comments but may do so either individually, in groups, or in some combination thereof. The current use of ''may,'' which the 2020 regulations changed from ''shall,'' creates ambiguity that could be read to mean that agencies have discretion in whether to respond to comments at all, not just the way they respond, *i.e.,* individually or in groups. Some comments on the 2020 proposed rule construed the change to ''may'' as weakening the longstanding requirement to respond to comments. The proposed change removes any ambiguity created by revisions to the paragraph in the 2020 regulations and is consistent with the longstanding requirement and expectation for agencies to respond to comments received on an EIS while also clarifying that agencies have discretion on how to respond to comments to promote the efficiency of the NEPA process.

In paragraph (c), CEQ proposes changes to clarify that when an agency uses an errata sheet, the agency must publish the entire final EIS, which would include the errata sheet, the draft EIS, and the comments with their responses. CEQ proposes these edits to reflect the typical Federal agency practice and to reflect the current requirement for electronic submission of EISs rather than the old practice of printing EISs for distribution.

F. Proposed Revisions To Update Part 1504, Pre-Decisional Referrals to the Council of Proposed Federal Actions Determined To Be Environmentally Unsatisfactory

1. Purpose (§ 1504.1)

CEQ proposes in § 1504.1(a) to add language encouraging agencies to engage early with each other to resolve interagency disagreements concerning proposed major Federal actions before such disputes are referred to CEQ. CEQ also proposes to add language clarifying that part 1504 establishes procedures for agencies to submit requests to CEQ for informal dispute resolution, expanding the purpose to reflect changes proposed in §§ 1504.2 and described in section II.F.2. This proposal is consistent with CEQ's ongoing role in promoting the use of environmental collaboration and conflict resolution,[85] and serving as a

[82] 2020 Response to Comments, *supra* note 63, at 326–27.

[83] *Id.* at 327.

[84] *Id.* at 328.

[85] *See* OMB & CEQ, Memorandum on Environmental Collaboration and Conflict Resolution (Sept. 7, 2012), *https://www.energy.gov/*

convener and informal mediator for interagency disputes. CEQ strongly encourages agencies to resolve disputes informally and as early as possible so that referrals under part 1504 are used only as a last resort. Early resolution of disputes is essential to ensuring an efficient and effective environmental review process.

In paragraph (b), which addresses EPA's role pursuant to section 309 of the Clean Air Act, CEQ proposes to strike the parenthetical providing the term ''environmental referrals,'' as this term is not used elsewhere in part 1504. Further, CEQ notes that EPA's section 309 authority is distinct from the ability of an agency to make a referral pursuant to this part. Finally, CEQ proposes to revise the second sentence in paragraph (c) to eliminate the passive voice to improve clarity.

2. Early Dispute Resolution (§ 1504.2)

As discussed further in section II.F.3, CEQ proposes to move the provisions in existing 40 CFR 1504.2 to § 1504.3(a) to repurpose § 1504.2 for a new section on early dispute resolution. CEQ proposes to add this section to codify the current practice of agencies to engage with one another and enlist CEQ to help resolve interagency disputes. The added text would codify CEQ's role in convening discussions, mediating issues, and recommending resolutions. While the proposed provisions in § 1504.2 are non-binding, they would serve to encourage agencies to use this informal process to resolve interagency disputes early in the process and provide transparency to the public that this process occurs.

Proposed paragraph (a) would encourage agencies to engage in interagency coordination and collaboration within planning and decision-making processes and to identify and resolve interagency disputes. Further, paragraph (a) would encourage agencies to elevate issues to appropriate agency officials or to CEQ in a timely manner that is consistent with the schedules for the proposed action established under § 1501.10.

Paragraph (b) would allow a Federal agency to request that CEQ engage in informal dispute resolution. When making such a request to CEQ, the agency must provide CEQ with a summary of the proposed action, information on the disputed issues, and agency points of contact. CEQ proposes this provision to codify the longstanding practice of CEQ helping to mediate and resolve interagency disputes outside of and well before the formal referral process (§ 1504.3) and to provide additional direction to agencies on what information CEQ needs to effectively mediate.

Paragraph (b) would provide CEQ with several options to respond to a request for informal dispute resolution, including requesting additional information, convening discussions, and making recommendations, as well as the option to decline the request.

3. Criteria and Procedure for Referrals and Response (§ 1504.3)

As noted in section II.F.2, CEQ proposes to move the criteria for referral currently set forth in 40 CFR 1504.2 to a new § 1504.3(a) and redesignate 40 CFR 1504.3(a) through (h) as § 1504.5(b) through (i), respectively. As a result of this consolidation, CEQ would revise the title of § 1504.3 to ''Criteria and procedure for referrals and response.'' The criteria and procedures for agencies to make a referral apply to agencies that make a referral under the NEPA regulations and do not apply to EPA when exercising its referral authority under section 309 of the Clean Air Act (42 U.S.C. 7609).

G. Proposed Revisions to NEPA and Agency Decision Making (Part 1505)

1. Record of Decision in Cases Requiring Environmental Impact Statements (§ 1505.2)

CEQ proposes modifications in § 1505.2 to align this section with other proposed changes to the regulations and clarify the alternatives agencies must identify in RODs. CEQ also proposes to modify the provision on mitigation.

As discussed further in this section, CEQ proposes to strike 40 CFR 1505.2(b), make 40 CFR 1505.2(a) an undesignated introductory paragraph in § 1505.2, and redesignate 40 CFR 1505.2(a)(1) through (3) as § 1505.2(a) through (c), respectively. In § 1505.2(b), CEQ proposes to restructure the first two sentences to improve readability and clarify that agencies must identify one or more environmentally preferable alternatives in the ROD, consistent with proposed changes to § 1502.14(f) requiring agencies to identify them in the EIS and § 1508.1(*l*), defining ''environmentally preferable alternative.'' Further, in the second sentence of paragraph (b), CEQ proposes to add ''environmental'' to the list of relevant factors upon which an agency may base discussion of preferences among alternatives. In paragraph (c), CEQ proposes to change ''avoid or minimize'' to ''mitigate'' in the first sentence for consistency with the remainder of the paragraph. CEQ also proposes to clarify that any mitigation must be enforceable, such as through permit conditions or grant agreements, if an agency includes it as a component of a proposed action and relies on its implementation to analyze the action's reasonably foreseeable environmental effects. Additionally, CEQ proposes to require agencies to identify the authority for enforceable mitigation, and adopt a mitigation and compliance plan consistent with § 1505.3(c).

CEQ proposes to strike 40 CFR 1505.2(b), which requires a decision maker to certify in the ROD that the agency has considered all of the alternatives, information, and analyses submitted under 40 CFR 1502.17(b) and states that such certification is entitled to a presumption that the agency has considered such information in the EIS. CEQ proposes to strike 40 CFR 1505.2(b) because it is redundant—the discussion in the ROD and the decision maker's signature on such document has long served to verify the agency has considered the EIS's analysis of the proposed action, alternatives, and effects, as well as the public comments received. Additionally, while CEQ agrees that agencies are entitled to a presumption of regularity under the tenets of generally applicable administrative law, this presumption does not arise from NEPA, and therefore, CEQ considers it inappropriate to address in the NEPA regulations.

Finally, CEQ proposes to strike 40 CFR 1505.2(b) consistent with the proposal to remove the exhaustion provision in 40 CFR 1500.3, as discussed in section II.B.2. As CEQ discussed in that section, CEQ now considers it more appropriately the purview of the courts to make determinations regarding exhaustion. The certification requirement would no longer be necessary since it was intended to trigger the exhaustion provision in judicial review.

2. Implementing the Decision (§ 1505.3)

CEQ proposes revisions to § 1505.3 to add provisions for mitigation and related monitoring and compliance plans. To accommodate the proposed changes, CEQ proposes to designate the undesignated introductory paragraph of 40 CFR 1505.3 as paragraph (a) and redesignate 40 CFR 1505.3(a) and (b) as § 1505.3(a)(1) and (a)(2), respectively.

CEQ proposes to add new § 1505.3(b) to encourage lead and cooperating agencies to incorporate, where

sites/default/files/OMB_CEQ_Env_Collab_Conflict_Resolution_20120907-2012.pdf; OMB & CEQ, Memorandum on Environmental Conflict Resolution (Nov. 28, 2005), *https://ceq.doe.gov/docs/ceq-regulations-and-guidance/regs/OMB_CEQ_Joint_Statement.pdf.*

appropriate, mitigation measures addressing a proposed action's significant adverse human health and environmental effects that disproportionately and adversely affect communities with environmental justice concerns. This addition would highlight the importance of considering environmental justice and addressing disproportionate effects through the NEPA process and the associated decision. CEQ proposes this addition based on public and agency feedback received during development of this proposed rule requesting that the regulations address mitigation of disproportionate effects. Additionally, this proposed change would encourage agencies to incorporate mitigation measures to address disproportionate burdens on communities with environmental justice concerns.

CEQ proposes to strike the text in paragraph (c) regarding mitigation and strike existing 40 CFR 1505.3(d) regarding publication of monitoring, replacing them with the new language in § 1505.3(c) regarding the contents of a monitoring and compliance plan. A revised paragraph (c) would require agencies to prepare a monitoring and compliance plan when the agency relies on and commits to mitigation in a ROD, FONSI, or separate document, which could be issued after the decision. This provision would require a plan for any mitigation relied upon and adopted as the basis for analyzing the reasonably foreseeable effects of a proposed action, not just mitigation to address significant effects. CEQ views this plan as necessary for an agency to conclude that it is reasonably foreseeable that a mitigation measure will be implemented. Further, the plan is necessary for the agency to conclude that the effects of the action without the mitigation measure are not reasonably foreseeable and, therefore, do not need to be analyzed and disclosed. CEQ does not propose to require a monitoring and compliance plan where an agency analyzes and discloses the effects of the action without the mitigation measure. In that circumstance, the agency would not rely on the mitigation measure as the basis for identifying reasonably foreseeable effects.

New paragraphs (c)(1) and (c)(1)(i) through (c)(1)(vi) would describe the contents of a monitoring and compliance plan and provide agencies flexibility to tailor plans to the complexity of the mitigation that the agency has incorporated into a ROD, FONSI, or other documents. Contents would include a description of the mitigation measures; the parties responsible for monitoring and implementation; how the information will be made publicly available, as appropriate; the timeframe for the mitigation; the standards for compliance; and how the mitigation will be funded. Agencies may tailor monitoring and compliance plans to the particular action, but they should contain sufficient detail to inform the participating and cooperating agencies and the public about relevant considerations, such as the magnitude of the environmental effects that would be subject to mitigation, the degree to which the mitigation represents an innovative approach, the degree of uncertainty about the efficacy of the mitigation, and other relevant facts that support a determination that the mitigation will be effective. Where a proposed action involves more than one agency, the lead and cooperating agencies should collaboratively develop a monitoring and compliance plan that clearly defines agency roles and avoids duplication of effort.

Requiring agencies to prepare a monitoring and compliance plan for mitigation relied upon in a decision is intended to address concerns that mitigation measures included in agency decisions are not always carried out or monitored for effectiveness. If it is reasonably foreseeable that a mitigation measure will not be effective, then the agency could not appropriately rely on the mitigation measure in determining that an effect is not significant. A monitoring and compliance plan would address this concern and support an agency relying on mitigation for purposes of accurately assessing the environmental effects of a proposed action, and, in some circumstances, concluding that a FONSI is appropriate.

A new paragraph (c)(2) would state that any new information developed through the monitoring and compliance plan would not require an agency to supplement their environmental documents solely because of this new information. This provision is intended to clarify that the existence of a monitoring and compliance plan by itself would not mean that the action to which it relates is an ongoing action if it would otherwise be considered completed; however, if an action remains to occur notwithstanding the monitoring and compliance plan, the agency may need to supplement its analysis in light of new information if the criteria for supplementation in § 1502.9(d) are met.

The proposed changes to § 1505.3 would be consistent with proposed revisions to 40 CFR 1505.2(c), which direct agencies to adopt and summarize a monitoring and enforcement program for any enforceable mitigation requirements or commitments for a ROD, and changes to § 1501.6(a) to clarify the use of mitigated FONSIs. The changes also would provide more consistency in the content of monitoring and compliance plans, increase transparency in the disclosure of mitigation measures, and provide the public and decision makers with relevant information about mitigation measures and the process to comply with them.

H. Proposed Revisions to Other Requirements of NEPA (Part 1506)

CEQ proposes multiple revisions to part 1506, as described in this section. As noted in section II.C.7, CEQ proposes to move 40 CFR 1506.6, ''Public involvement,'' to proposed § 1501.9, ''Public and governmental engagement.'' CEQ is not proposing changes to § 1506.2, Elimination of duplication with State, Tribal, and local procedures; § 1506.4, Combining documents; or § 1506.8, Proposals for legislation. CEQ invites comment on whether it should make changes to these sections or other changes to part 1506.

1. Limitations on Actions During NEPA Process (§ 1506.1)

CEQ proposes to edit § 1506.1(b) to provide further clarity on the limitations on actions during the NEPA process to ensure that agencies and applicants do not take actions that will adversely affect the environment or limit the choice of reasonable alternatives until an agency concludes the NEPA process.

CEQ is proposing to amend the last sentence in paragraph (b), which provides that agencies may authorize certain activities by applicants for Federal funding while the NEPA process is ongoing. To better align this provision with NEPA's requirements, CEQ proposes to add a clause to the sentence clarifying that such activities cannot limit the choice of reasonable alternatives, and the Federal agency must notify the applicant that the agency retains discretion to select any reasonable alternative or the no action alternative regardless of any potential prior activity taken by the applicant prior to the conclusion of the NEPA process. This proposal would provide additional clarity consistent with 40 CFR 1506.1(a) and the 2020 Response to Comments, which state that this provision allows certain activities to proceed, prior to a ROD or FONSI, so long as they do not have an adverse environmental impact or limit the

choice of reasonable alternatives.[86] It also is responsive to comments received on the 2020 rule expressing concern that the proposed language could allow pre-decisional activities to proceed that would inappropriately narrow the range of alternatives considered by an agency. To address this concern, these commenters requested that the CEQ clarify in the regulations that these pre-decisional activities cannot limit the range of alternatives an agency considers under NEPA.[87] CEQ's proposed amendments to this paragraph would provide clarity on this issue within the regulatory text.

CEQ also proposes to strike ''required'' in paragraph (c). This edit is consistent with § 1506.11, which encourages, but does not require, the use of programmatic environmental reviews.

2. Adoption (§ 1506.3)

The CEQ regulations have always allowed agencies to adopt all or part of an EIS. The 2020 regulations expanded the adoption provisions to codify longstanding agency practice of adopting EAs and explicitly allowed for adoption of other agencies' prior CE determinations. CEQ has heard from multiple stakeholders, including clean energy and other stakeholders, that CEQ should retain these provisions because they create efficiencies in the NEPA process. Conversely, other stakeholders, including environmental organizations, have raised concerns about potential abuse of the adoption process, especially for CE determinations. CEQ proposes changes to this provision to facilitate use of these efficiency mechanisms in an appropriate and transparent manner. CEQ proposes modifications to § 1506.3 to improve clarity, reduce redundancy, and ensure that when a Federal agency adopts an EIS, EA, or CE determination, the agency conducts an independent review to determine that the EIS, EA, or CE determination meets certain basic standards. CEQ also proposes to add new requirements regarding the adoption of another agency's CE determination to increase public transparency.

In paragraph (a), CEQ proposes to strike the language requiring an EIS, EA, or CE determination to meet relevant standards and instead capture the standards in paragraphs (b) through (d) addressing adoption of EISs, EAs, and CE determinations, respectively. CEQ proposes to replace this clause with a statement that requires adoption to be done ''consistent with this section.'' CEQ proposes to remove ''Federal'' as unnecessary and to make clear that agencies can adopt NEPA documents prepared by non-Federal entities that are doing so pursuant to delegated authority from a Federal agency. *See, e.g.,* 23 U.S.C. 327.

Accordingly, in paragraph (b), CEQ proposes to add introductory text clarifying the standard for adopting an EIS. The language would provide that an agency may adopt a draft or final EIS, or a portion of a draft or final EIS, if the adopting agency independently reviews the statement and concludes it meets the standards for an adequate statement pursuant to the CEQ regulations and the agency's NEPA procedures. In paragraph (b)(1), which addresses adoption of an EIS for actions that are substantially the same, CEQ proposes to insert ''and file'' after ''republish'' to improve consistency with § 1506.9 and because agencies must both publish the EIS and file it with EPA. Further in paragraph (b)(1), CEQ proposes to add text to clarify that agencies should supplement or reevaluate an EIS if the agency determines that the EIS requires additional analysis. For example, this may be necessary if an agency is adopting an EIS for an action that was evaluated 5 years earlier, and there is more recent data or updated information available on one of the categories of effects. In such instances, the agency would adopt the EIS, prepare a supplemental analysis reevaluating the particular category of effects for which updated information is available, and issue both for public comment. Similarly, if an action is not substantially the same and the adopting agency determines that the EIS requires supplemental analysis, the agency would treat the EIS as a draft, prepare the additional analysis, and publish the new draft EIS for notice and comment. Where a proposed action is not substantially the same, an agency must, at minimum, supplement the adopted EIS to ensure it covers its proposed action.

Additionally, in paragraph (b)(2), which addresses adoption of an EIS by a cooperating agency, CEQ proposes to clarify that this provision is triggered when a cooperating agency does not issue a joint or concurrent ROD consistent with § 1505.2. For example, this provision covers instances when a cooperating agency adopts an EIS for an action the cooperating agency did not anticipate at the time the EIS was issued, such as a funding action for a project that was not contemplated at the time of the EIS. In such instances, the cooperating agency may issue a ROD adopting the EIS of the lead agency without republication. CEQ proposes to strike the text at the end of paragraph (b)(2) regarding independent review because that standard would be captured in paragraph (b).

In paragraph (c), CEQ proposes to add introductory language to clarify the standard for adopting an EA, which mirrors the standard for adoption of an EIS. CEQ similarly proposes edits to align the process with EISs by clarifying that the adopting agency may adopt the EA, and supplement or reevaluate it as necessary, in its FONSI.

For additional clarity, CEQ proposes to add ''determinations'' to the title of paragraph (d). CEQ also proposes to revise this paragraph to improve readability and clarify that the adopting agency is adopting another agency's already made determination that a CE applies to a particular proposed action where the adopting agency's proposed action is substantially the same. This provision does not allow an agency to unilaterally use another agency's CE for an independent proposed action; rather, that process is addressed in § 1501.4(e).

To ensure that there is public transparency for adoption of CE determinations, like adoption of EAs and EISs, CEQ proposes to require agencies to document and publish their adoption of CE determinations, such as on their website. Proposed changes to paragraph (d)(1) would specify that agencies must document a determination that the proposed action is substantially the same as the action covered by the original CE determination, and there are no extraordinary circumstances present requiring preparation of an EA or EIS. Because agencies typically already make such determinations in the course of adopting CE determinations for actions that are substantially the same, CEQ does not view this documentation requirement as onerous or time consuming.

Finally, CEQ proposes to add paragraph (d)(2) requiring agencies to publicly disclose when they are adopting a CE determination. This proposed change is intended to increase transparency on use of CEs in response to feedback from stakeholders that they often do not know when an agency is proceeding with a CE. This adds a standard to adoption of CE determinations that is similar to the practice for adoption of EAs and EISs. Agencies, however, would have flexibility to determine how to make this information publicly available, including through posting on an agency's website.

[86] 2020 Response to Comments, *supra* note 63, at 356.

[87] *Id.* at 355.

3. Agency Responsibility for Environmental Documents (§ 1506.5)

CEQ proposes modification and additions to § 1506.5 to clarify the requirements related to a Federal agency's role in preparing environmental documents and for consistency with section 107(f) of NEPA, which requires agencies to prescribe procedures to allow project sponsors to prepare EAs and EISs under the agencies' supervision and to independently evaluate and take responsibility for such documents. The 2020 rule amended this provision to allow an applicant to prepare EISs on behalf of the agency; however, the 2023 amendments to NEPA make clear that agencies must establish procedures for project sponsors to prepare environmental documents, not the CEQ regulations. CEQ understands the 2023 amendments to NEPA to use the terms applicant and project sponsor interchangeably and, therefore, CEQ proposes to remove references to applicants from this section other than to cross-reference the requirement that agencies establish procedures in their agency NEPA procedures for project sponsors to prepare environmental documents. See section II.I.2. However, CEQ notes that applicants and project sponsors may still provide information to agencies so that they or their contractors may prepare environmental documents consistent with § 1506.5(b).

In paragraph (a), CEQ proposes to clarify that, regardless of who prepares an environmental document, the agency must ensure they are prepared with professional and scientific integrity using reliable data and resources, consistent with sections 102(2)(D) and (2)(E) of NEPA, and exercise its independent judgment to review, take responsibility for, and briefly document its determination that the document meets all necessary requirements and standards related to NEPA, the CEQ regulations, and the agency's NEPA procedures. Agencies do not need to document this determination separately and, for example, could include a certification statement in the environmental document.

Paragraph (b) would provide that agencies can authorize a contractor to draft a FONSI or ROD, but the agency is responsible for its accuracy, scope, and contents. Because a FONSI or ROD represents an agency's conclusions regarding potential environmental impacts and other aspects of a proposed action, CEQ proposes these changes to exclude applicants from directly preparing these documents and to clarify the role of contractors. A lead agency must prescribe procedures to allow a project sponsor to prepare an environmental assessment or an environmental impact statement, consistent with section 107(f) of NEPA, and CEQ proposes to require agencies to include these procedures as part of their agency NEPA procedures in § 1507.3(c)(12). Finalizing and verifying the contents of these decision documents is appropriately the responsibility of the Federal agency and is consistent with longstanding agency practice.

CEQ proposes to revise paragraph (b)(4) to clarify that the Federal agency is responsible for preparing a disclosure statement for the contractor to execute, specifying that the contractor does not have any financial or other interest in the outcome of the proposed action. The proposed language is generally consistent with the approach in the 1978 regulations.

Finally, CEQ proposes to remove the paragraph headings because they do not accurately or helpfully describe the contents of the paragraphs.

4. Further Guidance (§ 1506.7)

CEQ proposes to simplify § 1506.7(a) by deleting references to Executive Orders that have been revoked. CEQ will continue to provide guidance concerning NEPA and its implementation on an as-needed basis. Any such guidance will be consistent with NEPA, the CEQ regulations, and any other applicable requirements. Future guidance could include updates to existing CEQ guidance [88] or new guidance. CEQ also proposes to update paragraph (b) to reflect the date upon which a final rule is effective. If there is a conflict between existing guidance and an issued final rule, the final rule would prevail after the date upon which it becomes effective.

5. Proposals for Regulations (40 CFR 1506.9)

CEQ proposes to strike 40 CFR 1506.9, ''Proposals for regulations.'' The 2020 rule added this provision to allow agencies to substitute processes and documentation as part of the rulemaking process for corresponding requirements in these regulations.[89] Since 1978, the CEQ regulations have encouraged agencies to combine environmental documents with any other agency document to reduce duplication and paperwork (40 CFR 1506.4), and agencies also may combine procedural steps, for example, to satisfy the public comment requirements of a rulemaking process and NEPA. *See* § 1507.3(c)(5). As such, CEQ expects that the provision at 40 CFR 1506.9 is unnecessary to achieve the desired effect of improved efficiency. Removing this section would avoid confusion and controversy over whether the procedures of a separate process meet the requirements of CEQ's regulations. Further, courts have questioned whether separate regulatory processes can be a substitute for NEPA in some cases. *See e.g., Sierra Club* v. *Fed. Energy Regul. Comm'n,* 867 F.3d 1357, 1375 (D.C. Cir. 2017) (''[T]he existence of permit requirements overseen by another [F]ederal agency or [S]tate permitting authority cannot substitute for a proper NEPA analysis.''). Additionally, CEQ does not consider it appropriate to single out one particular type of action—rulemaking—for aligning or combining procedural steps. Indeed, one of the key objectives of agency NEPA procedures is to integrate the NEPA process into other agency processes. Therefore, CEQ suggests the more prudent approach is for agencies to combine NEPA reviews with other reviews for rulemaking, similar to longstanding agency practice to combine NEPA documents with other review processes, such as compliance with section 106 of the National Historic Preservation Act or section 7 of the Endangered Species Act, or set out processes in their NEPA procedures to comply concurrently with multiple legal requirements.

6. Filing Requirements (§ 1506.9)

CEQ proposes to redesignate 40 CFR 1506.10 as § 1506.9, which would restore the same numbering for this and subsequent sections used in the 1978 regulations. CEQ proposes to replace the acronym for EPA with the full name ''Environmental Protection Agency'' here and in § 1506.10, consistent with the format in the rest of the CEQ regulations. CEQ also proposes to clarify that agencies must notify EPA when they adopt an EIS consistent with § 1506.3(b). CEQ proposes this change to codify common practice and guidance from EPA.[90] EPA notification ensures initiation of the appropriate comment or review period. Such notification, even where a cooperating agency is adopting without public comment consistent

[88] *See* CEQ, *CEQ Guidance Documents, https://ceq.doe.gov/guidance/guidance.html.*

[89] 2020 Final Rule, *supra* note 36, at 43338–39.

[90] *See* EPA, *Environmental Impact Statement Filing Guidance, https://www.epa.gov/nepa/environmental-impact-statement-filing-guidance.* EPA must be notified when a Federal agency adopts an EIS to commence the appropriate comment or review period. If a Federal agency chooses to adopt an EIS written by another agency, and it was not a cooperating agency in the preparation of the original EIS, the EIS must be republished and filed with EPA.

with § 1506.3(b)(1), improves transparency to the public regarding the status of an EIS and also helps track the status of EISs across the Federal Government.

7. Timing of Agency Action (§ 1506.10)

To accommodate the change in numbering described in section II.H.6, CEQ proposes to renumber 40 CFR 1506.11 ''Timing of agency action'' to § 1506.10. CEQ proposes in paragraph (b) to change ''may not'' to ''shall not'' to eliminate a potential ambiguity. CEQ proposes changes to paragraph (c)(1) to update this provision to reflect current practices within Federal agencies. Specifically, CEQ proposes to change references to ''appeal processes'' to ''administrative review processes'' and add examples, which can include processes such as appeals, objections, and protests. CEQ further proposes updates to align the text to provide flexibility in timing to agencies that use these administrative review processes and clarify that such a process may be initiated either prior to or after the filing and publication of a final EIS with EPA depending on the specifics of the agency's authorities. Depending on the agency involved and their associated authorities, administrative review processes generally allow other agencies or the public to raise issues about a decision and make their views known. CEQ proposes to clarify that the period for administrative review of the decision and the 30-day review period prescribed in paragraph (b)(2) for when a ROD can be issued may run concurrently. CEQ proposes these changes to reflect changes in Federal agency regulations and procedures since this text was promulgated in 1978 and to allow for greater efficiency.

For example, the U.S. Department of Agriculture's Forest Service has an objections process outlined at 36 CFR part 218 where the public can object to a draft decision; these regulations replaced the prior appeal process formerly used by the agency. To initiate the objections process, Forest Service regulations require that the final EIS and a draft ROD be made available to the public, but the Forest Service does not have to publish the final EIS with EPA until the conclusion of the objections process. *See* 36 CFR 218.7(b). The objections process can take 120 to 160 days, during which the agency makes the final EIS widely available to the public. Allowing the agency to file the final EIS with EPA and issue a ROD at the same time as the conclusion of the objections process rather than waiting an additional 30 days following the official filing will add efficiency to the process. These proposed changes also would accommodate similar administrative review procedures. *See e.g.,* 43 CFR 1610.5–2 (outlining the Bureau of Land Management (BLM) protest procedures).

CEQ also proposes minor edits in paragraphs (d) and (e) for clarity and readability.

8. Emergencies (§ 1506.11)

Consistent with changes in the preceding sections, CEQ proposes to renumber 40 CFR 1506.12 ''Emergencies'' to § 1506.11. CEQ proposes to strike the last sentence stating other actions remain subject to NEPA review. This erroneously implies that actions covered by § 1506.11 are not subject to NEPA review. Instead, CEQ proposes to replace the sentence with language clarifying that alternative arrangements are not a waiver of NEPA; rather, they establish an alternative means for NEPA compliance.

This longstanding provision on emergencies has generated some confusion [91] as to whether, during emergencies, agency actions are exempted from NEPA review. CEQ proposes these changes to clarify that the regulations do not create a NEPA exemption; rather, they provide a pathway for compliance with NEPA where the exigencies of emergency situations do not provide sufficient time for an agency to complete an EIS for an action with significant environmental effects. As has been the long-standing practice, agencies may continue to determine how to proceed with actions to respond to emergencies that do not have significant environmental effects and that would ordinarily be analyzed through an EA. As discussed in section II.I.2, some agencies include procedures for addressing such situations in their agency NEPA procedures.

CEQ does not have the authority to exempt agency actions from NEPA, regardless of whether an emergency exists. The proposed changes to § 1506.11 clarify that CEQ does not offer ''alternative arrangements'' to circumvent appropriate NEPA analysis but rather allows Federal agencies to establish alternative means for NEPA compliance to ensure that agencies can act swiftly to address emergencies while also meeting their statutory obligations under NEPA. CEQ's proposal would clarify that when emergencies arise, § 1506.11 allows agencies to adjust the means by which they achieve NEPA compliance. This approach is also consistent with CEQ's guidance on NEPA and emergencies, updated in 2020.[92]

9. Innovative Approaches to NEPA Reviews (§ 1506.12)

CEQ proposes to add a new section to the regulations in § 1506.12 to allow CEQ to grant a request for modification to authorize Federal agencies to pursue innovative approaches to comply with NEPA and the regulations in order to address extreme environmental challenges. CEQ's intent is for this section to maximize agency flexibility, creativity, and efficiency while still meeting the requirements of NEPA and providing for sound environmental review. This is a new concept, distinct from the emergency provisions in § 1506.11, and different considerations apply for determining the existence of an extreme environmental challenge sufficient to trigger the proposed § 1506.12 than those for determining the existence of an emergency requiring alternative arrangements pursuant to § 1506.11. For example, an extreme environmental challenge might have a longer time horizon than is typical for an emergency action. As another example, it might be appropriate for an agency to determine that a forest ecosystem presenting a high risk of severe wildfire that could threaten water supplies presents extreme environmental challenges, even though restoration activities would take many years to complete. The intent of this approach is to allow for agencies to take innovative approaches when exploring how to address extreme environmental challenges, which could include, for instance, sea level rise or increased wildfire risk, or bolstering the resilience of infrastructure to increased disaster risk from the effects of climate change; water scarcity; degraded water or air quality; species loss; disproportionate and adverse effects on communities with environmental justice concerns; imminent or reasonably foreseeable loss of historic, cultural, or Tribal resources; and impaired ecosystem health.

Paragraph (a) would provide that the purpose of this section is to allow agencies to comply with NEPA using procedures modified from the requirements of these regulations to address extreme environmental challenges.

Paragraph (b) would require CEQ approval for any innovative approaches and make clear that approval does not waive the requirement to comply with

[91] 2020 Response to Comments, *supra* note 63, at 417–19.

[92] CEQ, Emergencies and the National Environmental Policy Act Guidance (Sept. 14, 2020), *https://ceq.doe.gov/docs/nepa-practice/emergencies-and-nepa-guidance-2020.pdf.*

the statute. Rather, this section establishes an alternative means for NEPA compliance to address extreme environmental challenges.

Paragraph (c) would outline what an agency must include in its request for approval of an innovative approach. Agencies would have to identify each provision of the regulations for which they are requesting modification and explain how the innovative approach they propose to ensure NEPA compliance. Agencies also must explain the extreme environmental challenge they are trying to address, why the alternative means are needed to address the challenge, and how the innovative approach would facilitate sound and efficient environmental review. Finally, agencies would need to consult with any potential cooperating agencies and include a summary of their comments with the request.

Paragraph (d) would provide CEQ's process for reviewing and approving such requests. Under this provision, CEQ would evaluate requests within 60 days and may choose whether to approve the approach, approve it with revision, or deny the request. Further, as is stipulated in paragraph (e), CEQ would post on its website all modification requests it has approved or denied.

Examples of innovative approaches that could be the basis for a request include new ways to use information technology; cooperative agreements or work with local communities; methods more fully incorporating, while protecting, Indigenous Knowledge; new ways to work with project proponents and communities to advance proposals; and innovative tools for engaging the public and providing public comment opportunities, which could enhance participation from communities with environmental justice concerns. CEQ acknowledges that the proposed regulations would not include explicit limits in any of these areas. The intent of proposed § 1506.12 is to help ensure that the regulations have the maximum ability to accommodate ideas not yet put forward to improve NEPA implementation. The proposed regulation would encourage innovation where needed to address extreme environmental challenges, consistent with the purposes and policies expressed in the NEPA statute including to ''promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of [humans],'' 42 U.S.C. 4321, and ''attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences,'' 42 U.S.C. 4331(b)(3). CEQ invites public comment on this proposed provision to determine if it is necessary. Specifically, CEQ would like input on whether such a provision is needed to address extreme environmental challenges and what Federal agencies would be able to carry out under this proposed provision that they cannot currently accomplish in the current regulations. CEQ also invites public comment on whether CEQ should add additional procedures or limitations to ensure that innovative approaches are used appropriately.

10. Effective Date (§ 1506.13)

CEQ proposes to remove the 2020 effective date and replace it with the date upon which a final rule is effective. CEQ notes that Federal agencies would not need to redo or supplement a completed NEPA review (*e.g.,* where a CE determination, FONSI, or ROD has been issued) as a result of the issuance of this rulemaking.

I. Proposed Revisions to Agency Compliance (Part 1507)

CEQ proposes substantive revisions to all sections in part 1507. CEQ invites comment on whether it should make other changes to this section.

1. Compliance (§ 1507.1)

CEQ proposes to add a second sentence to § 1507.1, restoring language from the 1978 regulations, to state that agencies have flexibility to adapt their implementing procedures to the requirements of other applicable laws. Restoring this language is consistent with the changes CEQ made to 40 CFR 1507.3 in its Phase 1 rulemaking to restore the agency discretion to tailor their NEPA procedures to their unique missions and contexts, creating opportunity for agencies to innovate and improve efficiency.

2. Agency Capability To Comply (§ 1507.2)

CEQ proposes edits to § 1507.2 to emphasize agencies' responsibilities under NEPA, including to incorporate the requirements added to section 102(2) of NEPA by the FRA, and require agencies to designate a Chief Public Engagement Officer. First, CEQ proposes to move the first sentence of 40 CFR 1507.2(a) to a new § 1507.2(b) and require agencies to identify a Chief Public Engagement Officer who would be responsible for facilitating community engagement across the agency and, where appropriate, the provision of technical assistance to communities. Next, CEQ proposes to redesignate 40 CFR 1507.2(b) and (c) as § 1507.2(c) and (d), respectively. Then, CEQ proposes to redesignate the existing 40 CFR 1507.2(d) through (f) as § 1507.2(h) through (j) and add a new paragraph (e) to require agencies to prepare environmental document with professional integrity consistent with section 102(2)(D) of NEPA. In a new paragraph (f), CEQ proposes to require agencies to make use of reliable data and resources, consistent with section 102(2)(E) of NEPA. And in a new paragraph (g), CEQ proposes to require agencies to study, develop, and describe technically and economically feasible alternatives, consistent with section 102(2)(F) of NEPA. Finally, in redesignated paragraph (j), CEQ proposes to delete the reference to E.O. 13807 because E.O. 13990 revoked E.O. 13807.

3. Agency NEPA Procedures (§ 1507.3)

CEQ proposes several updates to § 1507.3 to reorganize paragraphs to improve readability, consolidate related provisions, restore text from the 1978 regulations, and codify CEQ guidance on CEs.

In paragraphs (a) and (b), CEQ would update the effective date to reflect the effective date of a final rule. In paragraph (b), CEQ proposes to give agencies 12 months after the effective date to develop proposed procedures and initiate consultation with CEQ to implement the CEQ regulations. CEQ also proposes moving, with some modification, language from paragraph (c) to paragraph (b) for clarity and to improve organization since the language is generally applicable to all agency NEPA procedures. CEQ would clarify that proposed procedures should facilitate efficient decision making and ensure that agencies make decisions in accordance with the policies and requirements of NEPA.

In paragraph (b)(2), CEQ proposes to change ''adopting'' to ''issuing'' to avoid confusion with adoption under § 1506.3. CEQ also proposes to restore text from the 1978 regulations requiring agencies to continue to review their policies and procedures and revise them as necessary to be in full compliance with NEPA. The 2020 rule deleted this language as redundant to language added to 40 CFR 1507.3(b) requiring agencies to update their procedures to implement the final rule.[93] CEQ is proposing to restore this language because CEQ views the requirement for an agency to continue to review their policies and procedures as different than the requirement in paragraph (b) to initially update procedures consistent with a final rule.

[93] 2020 Final Rule, *supra* note 36, at 43340.

Further, restoring this requirement is consistent with the proposal in paragraph (c)(9) for agencies to review CEs at least every 10 years. CEQ proposes a new paragraph (b)(3) to explicitly clarify that, consistent with longstanding practice, the issuance of new agency procedures or an update to existing agency procedures is not subject to NEPA review. To align with these changes with paragraph (b) and its paragraphs, CEQ proposes to strike the first clause in 40 CFR 1507.3(e) because it is unnecessary and could create confusion and move the other text in 40 CFR 1507.3(e) into § 1507.3(c) as discussed below. This provision does not provide any additional direction given the regulations' longstanding existing requirements that agencies develop agency NEPA procedures, and CEQ determinations that they conform to the NEPA regulations. Further, its requirement that agency procedures ''comply'' with the CEQ regulations could be read to suggest that agencies must complete a NEPA review when establishing their procedures.

Paragraphs (c) and (c)(1) through (c)(10) would list the items that all agency NEPA procedures must include. CEQ proposes minor revisions to paragraphs (c)(1) through (c)(4) to improve clarity and conciseness. CEQ proposes to modify paragraph (c)(3) to clarify that procedures should integrate environmental review into agency decision-making processes so decision makers can make use of them in making the decision. CEQ proposes to modify paragraph (c)(5) to emphasize that combining environmental documents should be done to facilitate sound and efficient decision making and avoid duplication. CEQ proposes to strike the language from this paragraph allowing agencies to designate and rely on other procedures or documents to satisfy NEPA compliance. As discussed further in sections II.C.1 and II.C.2, CEQ has concerns about this language added by the 2020 rule to substitute other reviews as functionally equivalent for NEPA compliance, and therefore proposes to remove it.

To consolidate into one paragraph the required aspects of agency NEPA procedures, CEQ proposes to move 40 CFR 1507.3(e)(1), (e)(2), (e)(2)(i), and (e)(2)(iii) to paragraphs (c)(6), (c)(7), (c)(7)(i) and (c)(7)(ii), respectively, with minor wording modification for readability. CEQ proposes to move with modification 40 CFR 1507.3(e)(2)(ii), requiring agencies to establish CEs and identify extraordinary circumstances to paragraph (c)(8). CEQ proposes in paragraphs (c)(8)(i) through (c)(8)(iii) to include more specificity about the process for establishing new or revising existing CEs consistent with CEQ's 2010 CE guidance and agency practice. Paragraph (c)(8)(i) would include the existing requirement from 40 CFR 1507.3(e)(2)(i) that agencies identify when documentation is required for a determination that a CE applies to a proposed action. Paragraph (c)(8)(ii) would require agencies to substantiate new or revised CEs and make the documentation publicly available. This is consistent with the 2010 guidance and CEQ's longstanding practice requiring agencies to demonstrate that agency activities are eligible for CEs.[94] CEQ proposes to add paragraph (c)(8)(iii) to require agencies to describe how agencies will consider extraordinary circumstances; this requirement is currently addressed in existing 40 CFR 1507.3(c)(2)(ii).

CEQ proposes to add paragraph (c)(9) to require agencies to include in their NEPA procedures a process for reviewing their CEs every 10 years. This would codify recommendations in CEQ's guidance on establishing CEs,[95] which encourages agencies to review CEs periodically. While the guidance recommends every 7 years,[96] CEQ is proposing for review to occur at least every 10 years. In CEQ's experience, it can take an agency a year or more to conduct such a review and revision given the steps involved, including conducting the review, developing a proposal to update procedures to reflect the review, consulting with CEQ, soliciting public comment, developing final procedures, and receiving a CEQ conformity determination. Federal agencies should review their CEs for multiple reasons, including to determine if CEs remain useful, whether they should modify them, and to determine if circumstances have changed resulting in an existing category raising the potential for significant effects.

CEQ proposes to move 40 CFR 1507.3(e)(3) to paragraph (c)(10) without substantive change. Finally, CEQ proposes to move the requirement for agencies to explain in their NEPA procedures where interested persons can get information on EISs and the NEPA process from 40 CFR 1506.6(e) to § 1507.3(c)(11) and add a reference to EAs as well.

CEQ proposes to codify section 107(f) of NEPA in a new paragraph (c)(12) requiring agencies to include procedures, where applicable, to allow a project sponsor to prepare EAs and EISs consistent with § 1506.5. Since not all agency actions involve project sponsors, CEQ proposes to include ''where applicable'' to qualify this requirement. CEQ includes ''consistent with § 1506.5'' so that such procedures would ensure environmental documents prepared by project sponsors (or a contractor on the project sponsor's behalf) are prepared with professional and scientific integrity, and ensure that the agency independently evaluates and takes responsibility for the contents of such documents. It also would ensure agencies require project sponsors to execute a disclosure statement to address financial or other interests. In addition to procedures, agencies may provide project sponsors with guidance and assist in the preparation of the documents consistent with § 1506.5(b)(1). CEQ invites comment on whether it should include additional provisions that agencies should consider or address in establishing such procedures.

CEQ proposes to delete the provisions in 40 CFR 1507.3(d) and its paragraphs, which recommend agency procedures identify different classes of activities or decisions that may not be subject to NEPA. CEQ proposes to revise § 1507.3(d) to provide a list of items that agencies may include in their procedures, as appropriate, which would include, at paragraph (d)(1), identifying activities or decisions that are not subject to NEPA. Proposing to delete the specific categories of such activities or decisions is consistent with the proposed changes to § 1501.1. *See* section II.C.1 and II.C.2. Paragraph (d)(2) would allow agencies to include processes for emergency actions that would not result in significant environmental effects. This provision is similar to CEQ's own emergency process for EISs provided in § 1506.11 but relates to activities that would not require preparation of an EIS. Some agencies have programs that focus on these types of emergency actions and may need to consider special arrangements for their environmental assessments in these circumstances. These special arrangements could focus on the format of the documents, special distribution and public involvement procedures, and timing considerations. Some agencies have already established such processes in their procedures to ensure efficient NEPA compliance in an emergency. *See, e.g.,* 36 CFR 220.4(b); Dep't of Homeland Sec., Instruction Manual #023–01–001–01, Section VI.[97]

[94] CE Guidance, *supra* note 9.

[95] *Id.*

[96] *Id.* at 16.

[97] *https://www.dhs.gov/sites/default/files/publications/DHS_Instruction%20Manual%20023-*

Continued

CEQ proposes to move, without modification, 40 CFR 1507.3(f)(1) and (f)(2) to paragraphs (d)(3) and (d)(4), respectively. CEQ proposes to remove 40 CFR 1507.3(f)(4) regarding combining the agency's EA process with its scoping process as unnecessary. Section 1501.5(j) clarifies that agencies can employ scoping at their discretion when it will improve the efficiency and effectiveness of EAs, including combining scoping with a comment period on a draft EA. In addition, CEQ proposes to remove, as superfluous, the first sentence of 40 CFR 1507.3(f)(3) regarding lengthy periods between an agency's decision to prepare an EIS and actual preparation, as the regulations do not prescribe specific timelines for preparation of environmental documents. As discussed in section II.D.3, CEQ proposes to move the second sentence of 40 CFR 1507.3(f)(3) regarding supplemental notices when an agency withdraws, cancels, or otherwise ceases the consideration of a proposed action before completing an EIS to § 1502.4(f) with modifications.

Finally, as discussed in section II.C.3, CEQ is proposing to strike 40 CFR 1507.3(f)(5) and replace it with a provision in § 1501.4(e) that is consistent with the process established by section 109 of NEPA for adoption or use of another agency's CE.

4. Agency NEPA Program Information (§ 1507.4)

CEQ proposes revisions to § 1507.4, which describes the use of agency websites and other information technology to promote transparency and efficiency in the NEPA process. In paragraph (a), CEQ proposes revisions to remove ''environmental'' before ''documents'' because ''environmental documents'' is a defined term, and the intent of the sentence is to refer to NEPA-related information and documents more broadly; CEQ proposes the same edit in paragraph (a)(1). CEQ also proposes to require agencies to provide on their websites or other information technology tools (to account for new technologies) their agency NEPA procedures and a list of EAs and EISs that are in development and complete. CEQ proposes to revise paragraph (a)(2) to encourage agencies to post their environmental documents to their websites. CEQ proposes to encourage rather than simply allow agencies to include the information listed in paragraphs (a)(1) through (a)(4). Finally, CEQ proposes edits to paragraph (b), which promotes interagency coordination of environmental program websites and shared databases, to provide agencies with additional flexibility and clarify that the section is not limited to the listed technology.

J. Proposed Revisions to Definitions (Part 1508)

Within part 1508, CEQ proposes revisions to the definitions of ''cooperating agency,'' ''effects'' or ''impacts,'' ''environmental assessment,'' ''environmental document,'' ''environmental impact statement,'' ''finding of no significant impact,'' ''human environment,'' ''lead agency,'' ''major Federal action,'' ''mitigation,'' ''notice of intent,'' ''page,'' ''scope,'' and ''tiering.'' CEQ proposes to add definitions for ''environmental justice,'' ''environmentally preferable alternative,'' ''extraordinary circumstances,'' ''joint lead agency,'' ''participating Federal agency,'' ''programmatic environmental document,'' and ''significant effects.''

CEQ does not propose substantive edits to any other definitions, but would redesignate the paragraphs to keep the list of terms in alphabetical order. CEQ invites comment on whether CEQ should modify other definitions or add new definitions. In particular, CEQ invites comment on whether it should define any additional terms used in NEPA, as amended by the FRA, including ''applicant'' or ''project sponsor.'' CEQ is not proposing to separately define the phrase ''communities with environmental justice concerns,'' but intends that phrase would mean communities that do not experience environmental justice as defined in § 1508.1(k). CEQ is particularly interested in comment on whether to provide a separate definition of ''communities with environmental justice concerns,'' and if so, how the regulations should define that term.

1. Cooperating Agency (§ 1508.1(e))

CEQ proposes to revise the definition of ''cooperating agency'' in § 1508.1(e) for clarity and consistency with the definition of ''cooperating agency'' in section 111(2) of NEPA defining this term to mean ''any Federal, State, Tribal, or local agency with jurisdiction by law or special expertise that has been designated as a cooperating agency by the lead agency . . . .''

2. Effects or Impacts (§ 1508.1(g))

In § 1508.1(g), CEQ proposes to make clarifying edits and to add and modernize examples. Paragraph (g)(4) lists common types of effects that may arise during NEPA review. CEQ proposes to update the list to add disproportionate and adverse effects to communities with environmental justice concerns and climate change-related effects. For climate change effects, CEQ proposes to clarify that this can include both the contributions to climate change from a proposed action and its alternatives as well as the potential effects of climate change on the proposed action and its alternatives. These changes would update the definition to include effects that have been an important part of NEPA analysis for more than a decade and will continue to be relevant, consistent with best available science and NEPA's requirements. Also, CEQ proposes these changes in response to comments received during the Phase 1 rulemaking that the definition of ''effects'' or ''impacts'' should explicitly address environmental justice and climate change.[98]

3. Environmental Assessment (§ 1508.1(h))

CEQ proposes to update the definition of ''environmental assessment'' in § 1508.1(h) for consistency with sections 106(b)(2) and 111(4) of NEPA, 40 CFR 1501.5, and longstanding agency practice. CEQ proposes to strike ''prepared by'' and change it to ''for which a Federal agency is responsible'' for consistency with section 107(f) of NEPA and § 1506.5, which allow a contractor or project sponsor (following agency issuance of procedures) to prepare an EA but requires that the agency take responsibility for the accuracy of its contents irrespective of who prepares it. This change would be consistent with longstanding agency practice to allow applicants and contractors to prepare EAs, so long as the agency is ultimately responsible for the contents.

To improve readability, CEQ proposes edits to add text from § 1501.5 clarifying that an agency prepares an EA when a proposed action is not likely to have a significant effect or the significance of the effects is unknown. CEQ also proposes to simplify language in the rest of the paragraph by deleting superfluous text. These proposed changes do not alter the intention that an EA is used to support an agency's determination whether to prepare an EIS (part 1502) or issue a FONSI (§ 1501.6).

4. Environmental Document (§ 1508.1(i))

CEQ proposes to add ''record of decision'' to the definition of ''environmental document'' in

01-001-01%20Rev%2001_508%20Admin%20Rev.pdf.

[98] Phase 1 Response to Comments, *supra* note 48, at 87, 99.

§ 1508.1(i) for clarity. CEQ also proposes to add a documented CE determination to the definition to reflect the longstanding agency practice of documenting some CE determinations. This change also is consistent with the change CEQ proposes to §§ 1501.4 and 1507.3 to add references to CE determinations. Therefore, for clarity and efficiency, CEQ is proposing to incorporate documented CE determinations into the definition of ''environmental document.'' CEQ notes that section 111(5) of NEPA defines ''environmental document'' more narrowly to only include EISs, EAs, and FONSIs. However, CEQ is proposing to retain and expand the regulatory definition since the term is used more broadly in the CEQ regulations.

5. Environmental Impact Statement (§ 1508.1(j))

CEQ proposes to change ''as required'' to ''that is required'' in the definition of EIS in § 1508.1(j) for consistency with the definition of ''environmental impact statement'' in section 111(6) of NEPA.

6. Environmental Justice (§ 1508.1(k))

CEQ proposes to add a new definition of ''environmental justice'' at § 1508.1(k). This definition would align with the definition set forth in section 2(b) of E.O. 14096.[99] This provision would define ''environmental justice'' as the just treatment and meaningful involvement of all people so that they are fully protected from disproportionate and adverse human health and environmental effects and hazards, and have equitable access to a healthy, sustainable, and resilient environment. The proposed definition of environmental justice uses the phrase ''cumulative impacts,'' rather than the phrase ''cumulative effects,'' which are used elsewhere in the proposed regulations. That is because the phrase ''cumulative impacts'' has a meaning in the context of environmental justice relating to the aggregate effect of multiple stressors and exposures on a person, community, or population. *See, e.g.,* Environmental Protection Agency, Cumulative Impacts Research: Recommendations for EPA's Office of Research and Development (2022). CEQ views the evolving science on cumulative impacts as sufficiently distinct from the general meaning of cumulative effects under the NEPA regulations that using a different term could be helpful to agencies and the public. CEQ invites comment on this approach.

[99] E.O. 14096, *supra* note 20, at 25253.

7. Environmentally Preferable Alternative (§ 1508.1(*l*))

CEQ proposes to add a new definition of ''environmentally preferable alternative'' at § 1508.1(*l*). Since 1978, the CEQ regulations have required agencies to identify the environmentally preferable alternative or alternatives in the ROD (§ 1505.2(b)). While the regulations did not define the term, CEQ's Forty Questions document provided an explanation, upon which CEQ has based the proposed definition.[100] The environmentally preferable alternative is the alternative that will best promote the national environmental policy as expressed in section 101 of NEPA. 42 U.S.C. 4331. Application of the term ''environmentally preferable alternative'' is also described in § 1502.14(f) and discussed in section II.D.9.

8. Extraordinary Circumstances (§ 1508.1(m))

CEQ proposes to add a definition of ''extraordinary circumstances'' at § 1508.1(m). The 1978 regulations included the meaning of extraordinary circumstances in the definition of ''categorical exclusion'' at 40 CFR 1508.4 (2019), which the 2020 rule moved to 40 CFR 1501.4(b) (describing how to apply extraordinary circumstances when considering use of a CE) and 40 CFR 1507.3(e)(2)(ii) (requiring agencies to establish extraordinary circumstances for CEs in their procedures).[101] CEQ proposes to create a standalone definition of ''extraordinary circumstances'' to improve clarity when this term is used throughout the rule.

CEQ also proposes to add several examples of extraordinary circumstances to help agencies and the public understand common situations that agencies may consider in determining whether application of a CE is appropriate. The examples would include impacts on sensitive environmental resources, disproportionate and adverse effects on communities with environmental justice concerns, effects associated with climate change, and effects on historic properties or cultural resources. This list of examples would not be exclusive, and agencies would continue to have the discretion to identify extraordinary circumstances in their NEPA implementing procedures that are specific and appropriate to their particular actions and CEs consistent with § 1507.3.

[100] Forty Questions, *supra* note 4.

[101] 2020 Final Rule, *supra* note 36, at 43322, 43342–43.

9. Finding of No Significant Impact (§ 1508.1(o))

In the definition of FONSI in § 1508.1(o), CEQ proposes to insert ''agency's determination that and'' after ''presenting the'' for consistency with the definition of FONSI in section 111(7) of NEPA, which defines the term to mean ''a determination by a Federal agency that a proposed agency action does not require the issuance of an environmental impact statement.''

10. Human Environment or Environment (§ 1508.1(p))

CEQ proposes to clarify that ''human environment'' and ''environment'' are synonymous in the regulations given that the latter is the more commonly used term. CEQ proposes a minor edit to ''human environment'' in § 1508.1(p) to remove ''of Americans'' after ''present and future generations.'' This minor edit improves consistency with NEPA in section 101(a), which speaks more generally about the impact of people's ''activity on the interrelations of all components of the natural environment'' and the need ''to create and maintain conditions under which [humans] and nature can exist in productive harmony.'' 42 U.S.C. 4331(a).

In the 2020 rule, CEQ changed ''people'' to ''of Americans,'' explaining that it was done to be consistent with section 101(a) of NEPA.[102] However, CEQ now considers this explanation to overlook the context in which the phrase ''present and future generations of Americans'' is used in section 101(a). That paragraph of the Act refers to Americans at the end of the last sentence after using the broader term ''man'' three times. A reasonable interpretation is that human environment refers broadly to the interrelationship between people and the environment. The phrase ''present and future generations of Americans'' is used in a narrower context to ''fulfill the social, economic, and other requirements of present and future generations of Americans.'' 42 U.S.C. 4331(a).

11. Joint Lead Agency (§ 1508.1(q))

CEQ proposes to add a definition for ''joint lead agency'' consistent with the usage of that term in section 107(a)(1)(B) of NEPA and § 1501.7(b) and (c).

[102] *Id.* at 43344–45.

12. Lead Agency (§ 1508.1(s))

CEQ proposes to revise the definition of ''lead agency'' for consistency with the definition of ''lead agency'' in section 111(9) of NEPA and to expand the definition of ''lead agency'' in § 1508.1(s) to also include EAs, consistent with longstanding practice.

13. Major Federal Action (§ 1508.1(u))

CEQ proposes to move the definition of ''major Federal action'' currently provided in 40 CFR 1508.1(q) to § 1508.1(u), revise it to clarify the list of example activities or decisions that meet the definition, and revise the list of exclusions from the definition consistent with section 111(10) of NEPA. CEQ notes that the determination of whether an activity or decision is a major Federal action is a fact-specific analysis that agencies have long engaged in to determine where they have substantial control and responsibility to consider environmental effects in their decision making.

CEQ proposes to reorder and revise the definition to list the examples of activities or decisions that may be included in the definition of ''major Federal action'' in paragraph (u)(1), redesignating current 40 CFR 1508.1(q)(3)(i) through (q)(3)(iv) as paragraphs (u)(1)(ii) through (u)(1)(v). To paragraph (u)(1), CEQ proposes to revise the current example in 40 CFR 1508.1(q)(2) in paragraph (u)(1)(i) and add one example of potential major Federal actions.

First, CEQ proposes to strike 40 CFR 1508.1(q)(2) and replace it with paragraph (u)(1)(i) to include the granting of authorizations such as permits, licenses, and rights-of way. CEQ proposes to strike the existing examples since regulated activities would be addressed in this revised example, and the others are redundant to the other examples listed in paragraphs (u)(1)(ii) through (u)(1)(vi).

Second, CEQ proposes to revise the phrase ''connected agency decisions'' to ''related agency decisions'' in paragraph (u)(1)(iv) to clarify that the concept in this paragraph is not meant to refer to ''connected actions'' as defined in § 1501.3. CEQ considers this a non-substantive, clarifying change to avoid any confusion with connected actions.

Third, CEQ proposes to revise paragraph (u)(1)(v) to change ''approval of'' to ''carrying out'' specific projects to address projects carried out directly by a Federal agency. CEQ proposes to strike ''located in a defined geographic area'' from the example of management activities; while this is merely an example, CEQ is concerned it could be read as limiting. CEQ also proposes to strike the sentence regarding permits and regulatory decisions as this would be addressed by the example in paragraph (u)(1)(i).

Fourth, CEQ proposes to add a new example at § 1508.1(u)(1)(vi) to explain when Federal financial assistance is a major Federal action. Generally, Federal financial assistance, other than minimal Federal funding, is a major Federal action where the Federal agency has authority and discretion over the financial assistance in a manner that could address environmental effects from the activities receiving the financial assistance. In such circumstances, the agency has sufficient control and responsibility over the use of the funds or the effects of the action for the decision to provide financial assistance to constitute a major Federal action consistent with the definition in section 111(10) of NEPA. This includes circumstances where the agency could deny the financial assistance, in whole or in part, due to environmental effects from the activity receiving the financial assistance, or could impose conditions on the financial assistance that could address the effects of such activity.

To improve clarity and ensure appropriate application of NEPA, CEQ proposes this example of what a major Federal action may include. CEQ considers that, other than for minimal Federal Funding, where an agency has substantial control and responsibility over a recipient's environmental effects or sufficient discretion to consider the environmental effects when making decisions, the appropriate approach is for agencies to identify the corresponding scope of analysis rather than excluding an activity or decision from NEPA review altogether. For example, if a Federal agency operates a loan guarantee program, the agency may have discretion in the types of activities to which it might issue a loan guarantee. A NEPA review that analyzes the environmental effects of potential project types could help inform how the agency designs the program. Depending on the terms of the loan guarantee program, the agency may have substantial control and responsibility over the use of the funds such that an environmental analysis can inform the decision making. As noted in section II.C.2 and earlier in this section, this is a fact-specific analysis agencies undertake based on the specifics of their authority for a particular action.

In § 1508.1(u)(2), CEQ proposes to replace the exclusions currently in 40 CFR 1508.1(q)(1)(i) through (vi) with the exclusions from the definition of major Federal action codified in the definition in section 111(10)(B) of NEPA. Paragraph (u)(2)(i)(A) and (B) would include the exclusion of non-Federal actions with no or minimal funding; or with no or minimal Federal involvement where the agency cannot control the outcome of the project consistent with section 111(10)(B)(i) of NEPA. These exclusions would replace the current exclusion in 40 CFR 1508.1(q)(1)(vi), which CEQ proposes to strike. CEQ invites comment on whether it should add additional provisions to the regulations to implement the ''minimal Federal funding'' exclusion in § 1508.1(u)(2)(i)(A). Agencies currently evaluate the provision of minimal Federal funding based on specific factual contexts. CEQ is interested in whether additional procedures, including thresholds for the amount or proportion of Federal funding necessary for an agency action to constitute major Federal action, could increase predictability while ensuring that Federal agencies do not overlook effects to vital components of the human environment, including the health of children and vulnerable populations, drinking water, communities with environmental justice concerns, and similar considerations.

Paragraph (u)(2)(ii) would include the exclusion of funding assistance solely in the form of general revenue sharing funds consistent with section 111(10)(B)(ii) of NEPA. This exclusion would replace the current, similar exclusion in 40 CFR 1508.1(q)(1)(v), which CEQ proposes to strike.

Paragraph (u)(2)(iii) would include the exclusion of loans, loan guarantees, or other forms of financial assistance where a Federal agency does not exercise sufficient control and responsibility over the subsequent use of such financial assistance or the effects of the action, consistent with section 111(10)(B)(iii) of NEPA.

Paragraph (u)(2)(iv) would include the exclusion of certain business loan guarantees provided by the Small Business Administration, consistent with section 111(10)(B)(iv) of NEPA. These exclusions would replace the current, similar exclusion in 40 CFR 1508.1(q)(1)(vii), which CEQ proposes to strike. In particular, CEQ proposes to strike the example currently in 40 CFR 1508.1(q)(1)(vii) for farm ownership and operating loan guarantees by the Farm Service Agency pursuant to 7 U.S.C. 1925 and 1941 through 1949. CEQ considers it best left to agencies to identify exclusions from the definition of major Federal action absent specific statutory authority like those for the Small Business Administration loan guarantees.

Next, CEQ proposes to move the existing exclusions, currently in 40 CFR 1508.1(q)(1)(iv), (q)(1)(i), and (q)(1)(ii) to paragraphs (u)(2)(v) through (u)(2)(vii), respectively. Section 111(10)(B)(v) through (vii) of NEPA codified these exclusions. Paragraph (u)(2)(v) would exclude bringing judicial or administrative civil or criminal enforcement actions. Paragraph (u)(2)(vi) would exclude extraterritorial activities or decisions.[103] Paragraph (u)(2)(vii) would exclude activities or decisions that are non-discretionary. CEQ notes that there may be activities or decisions that are partially non-discretionary. In such circumstances, an agency may conclude that the non-discretionary components of an activity or decision are not major Federal actions and exclude the non-discretionary components from analysis. In such circumstances, the agency would consider the discretionary components of the activity or decision. For example, if a statute mandated an agency to make an affirmative decision once a set of criteria are met, but the agency has flexibility in how to meet those criteria, the agency still has some discretion to consider alternatives and effects. Similarly, if a statute directs an agency to take an action, but the agency has discretion in how it takes that action, the agency can still comply with NEPA while carrying out its statutory mandate.

CEQ proposes to move the exclusion regarding final agency actions from 40 CFR 1508.1(q)(1)(iii) to § 1508.1(u)(2)(viii) and make changes for consistency with section 106(a)(1). While section 106(a)(1) of NEPA includes this as a threshold factor for not requiring an EIS or EA, it is consistent with longstanding caselaw to exclude non-final agency actions from the definition of major Federal action. Therefore, CEQ proposes to include this as a threshold consideration as well as an exclusion from the definition of major Federal action.

Finally, CEQ proposes a new exclusion in § 1508.1(u)(2)(ix) for activities or decisions for projects approved by a Tribal Nation that occur on or involve land held in trust or restricted status when the activities involve no Federal funding or other Federal involvement. Recognizing the unique circumstances facing Tribal Nations due to the United States holding land in trust for them or the Tribal Nation holding land in restricted status, CEQ proposes this exclusion to clarify that activities or decisions for projects approved by a Tribal Nation on trust lands are not major Federal actions where such activities do not involve Federal funding or other Federal involvement. Tribal leaders raised this issue during consultations that CEQ held on its NEPA regulations and voiced concerns that the NEPA process placed Tribal Nations in a disadvantageous position relative to State and local governments because of the United States' ownership interest in Tribal lands. Categories of activities on trust lands that typically will not constitute major Federal actions include transfer of existing operation and maintenance activities of Federal facilities to Tribal groups, water user organizations, or other entities; human resources programs such as social services, education services, employment assistance, Tribal operations, law enforcement, and credit and financing activities not related to development; self-governance compacts for Bureau of Indian Affairs programs; service line agreements for an individual residence, building, or well from an existing facility where installation will involve no clearance of vegetation from the right-of-way other than for placement of poles, signs (including highway signs), or buried power/cable lines; and approvals of Tribal regulations or other documents promulgated in exercise of Tribal sovereignty, such as Tribal Energy Resource Agreements, certification of a Tribal Energy Development Organization, Helping Expedite and Advance Responsible Tribal Homeownership Act Tribal regulations, Indian Trust Asset Reform Act Tribal regulations and trust asset management plans, and Tribal liquor control ordinances.

14. Mitigation (§ 1508.1(w))

CEQ proposes three edits to the definition of ''mitigation'' in § 1508.1(w). First, CEQ proposes to change ''nexus'' to the more commonly used word ''connection'' to describe the relationship between a proposed action or alternatives and any associated environmental effects. Second, CEQ proposes to delete the sentence that NEPA ''does not mandate the form or adoption of any mitigation'' because this sentence is unnecessary and could mislead readers by not acknowledging that agencies may use other authorities to require mitigation or may incorporate mitigation in mitigated FONSIs (§ 1501.6) and RODs (§ 1505.2). Third, CEQ proposes to add the clause ''in general order of priority'' to the sentence, ''Mitigation includes'' which introduces the list of mitigation types. This change would clarify that the types of mitigation provided in paragraphs (u)(1) though (u)(5) are listed in general order of priority, consistent with the familiar ''mitigation hierarchy.''[104] This list was prioritized in the 1978 regulations with avoidance coming before other types of mitigation and this proposed addition highlights that intent, which is consistent with longstanding agency practice.[105]

15. Notice of Intent (§ 1508.1(y))

CEQ proposes to modify the definition of notice of intent to include environmental assessments, as applicable. CEQ proposes this change for consistency with § 1501.5(j), which provides that agencies may issue an NOI for an EA where it is appropriate to improve efficiency and effectiveness, and § 1501.10(b)(3)(iii), which sets forth one of the three potential starting points from which deadlines are measured for environmental assessments consistent with section 107(g)(1)(B)(iii).

[103] CEQ notes that the statutory exclusion of these activities from the definition of major Federal action and therefore NEPA review does not change the scope of environmental effects that agencies should assess for actions that are subject to NEPA review.

[104] *See e.g.,* U.S. Dep't of the Interior, A Strategy for Improving the Mitigation Policies and Practices of the Department of the Interior 2–3 (Apr. 2014), *https://www.doi.gov/sites/doi.gov/files/migrated/news/upload/Mitigation-Report-to-the-Secretary_FINAL_04_08_14.pdf* (discussing the development of a ''mitigation hierarchy''—which starts with avoidance—in the implementation of NEPA and the Clean Water Act); Bureau of Land Mgmt., H–1794–1, Mitigation Handbook (P) 2–1 (Sept. 22, 2021), *https://www.blm.gov/sites/default/files/docs/2021-10/IM2021-046_att2.pdf* (citing CEQ regulations and noting that the ''five aspects of mitigation (avoid, minimize, rectify, reduce/eliminate, compensate) are referred to as the mitigation hierarchy because they are generally applied in a hierarchical manner''); U.S. Env't Prot. Agency & U.S. Dep't of Def., Memorandums of Agreement (MOA); Clean Water Act Section 404(b)(1) Guidelines; Correction, 55 FR 9210, 9211 (Mar. 12, 1990) (noting that under section 404 of the Clean Water Act, the Army Corps of Engineers evaluates potential mitigation efforts sequentially, starting with avoidance, minimization, and then compensation).

[105] *See, e.g.,* 10 CFR 900.3 (defining a regional mitigation approach under NEPA as ''an approach that applies the mitigation hierarchy (first seeking to avoid, then minimize impacts, then, when necessary, compensate for residual impacts)''); Presidential Memorandum, Mitigating Impacts on Natural Resources From Development and Encouraging Related Private Investment, 80 FR 68743, 68745 (Nov. 6, 2015) (addressing five agencies and noting that, ''[a]s a practical matter, [mitigation is] captured in the terms avoidance, minimization, and compensation. These three actions are generally applied sequentially . . . .''); Fed. Highway Admin., *NEPA and Transportation Decisionmaking: Questions and Answers Regarding the Consideration of Indirect and Cumulative Impacts in the NEPA Process* Question 9, *https://www.environment.fhwa.dot.gov/nepa/QAimpact.aspx* (describing the importance of ''sequencing,'' which refers to the process of prioritizing avoidance and minimization of effects over replacement or compensation for NEPA mitigation efforts).

16. Page (§ 1508.1(z))

CEQ proposes to modify the definition of ''page'' consistent with section 107(e) of NEPA to exclude citations from the page limits for EISs and EAs. CEQ proposes to retain the exclusions for maps, diagrams, graphs, tables, and other means of graphically displaying quantitative or geospatial information from the definition of ''page'' to facilitate better NEPA documents. While agencies could move these visual representations of information to appendices, which could come at the end of an EIS or the end of EIS chapters, CEQ is concerned that this will make the documents less functional to decision makers and the public. Further, such graphical displays themselves could be considered appendices consistent with the ordinary definition of appendix—supplementary material usually attached at the end of a piece of writing.[106] CEQ invites comment on its proposed definition of ''page.''

17. Participating Federal Agency (§ 1508.1(bb))

CEQ proposes to add a definition of ''participating Federal agency'' to § 1508.1(bb) and define it consistent with the definition of the same term in section 111(8) of NEPA.

18. Programmatic Environmental Document (§ 1508.1(cc))

CEQ proposes to add a definition of ''programmatic environmental document'' to § 1508.1(cc) and define it consistent with the definition of the same term in section 111(11) of NEPA.

19. Scope (§ 1508.1(ii))

CEQ proposes to expand the definition of ''scope'' to include EAs and revise the definition to include both the range and breadth of the actions, alternatives, and effects to be considered in an EIS or EA, consistent with CEQ's proposed relocation of the discussion of scope in § 1501.3(b). As discussed further in section II.C.2, agencies have long examined the scope of their actions to determine what alternatives and effects they must analyze. This is a fact-specific analysis that agencies undertake informed by their statutory authority and control and responsibility over the activity. CEQ also proposes to strike the last sentence regarding tiering because it is not definitional language and is unnecessary because this concept is more fully addressed in § 1501.11.

20. Significant Effects (§ 1508.1(kk))

CEQ proposes to add a definition for ''significant effects'' to provide a definition for those effects that are of vital importance in the NEPA process in determining the appropriate level of review. The proposed definition would align with the restoration of the context and intensity factors for determining significance in § 1501.3(d). CEQ proposes to define ''significant effects'' as adverse effects identified by an agency as significant based on the criteria set forth in § 1501.3(d). This would clarify that beneficial effects are not significant effects as the phrase is used in NEPA and, therefore, do not require an agency to prepare an EIS. CEQ proposes this as an alternative approach to the proposal in § 1501.3(d)(2)(i) where an action ''does not'' require an EIS when it would result only in significant beneficial effects. If CEQ includes this definition in the final rule, this approach would mean that an agency would not need to prepare an EIS if a proposed action's effects are exclusively beneficial. However, irrespective of the level of NEPA review, agencies would still need to analyze both adverse and beneficial effects in NEPA documents if they are reasonably foreseeable. CEQ invites comment on the definition, specifically on the inclusion of ''adverse'' in the definition, and comments on whether the approach in § 1501.3(d)(2)(i) or § 1508.1(kk) is preferred and the reasons why. Finally, CEQ invites the public to submit any examples of EAs or EISs where there were significant effects that were purely beneficial.

21. Tiering (§ 1508.1(mm))

CEQ proposes to revise the definition of tiering to cross reference the process as set forth in § 1501.11. CEQ is proposing this revision to avoid any potential inconsistencies between the definition and the provisions of § 1501.11.

III. Rulemaking Analyses and Notices

A. Executive Order 12866, Regulatory Planning and Review

E.O. 12866 provides that the Office of Information and Regulatory Affairs will review all significant rules.[107] E.O. 13563 reaffirms the principles of E.O. 12866, calling for improvements in the Federal Government's regulatory system to promote predictability, reduce uncertainty, and use the best, most innovative, and least burdensome tools for achieving regulatory objectives.[108] This proposed rule is a significant regulatory action under section 3(f)(1) of E.O. 12866 that CEQ submitted to OMB for review. The proposed changes would improve the CEQ regulations to benefit agencies and the public. Furthermore, an effective NEPA process can save time and reduce overall project costs by providing a clear process for evaluating alternatives and effects, coordinating agencies and relevant stakeholders including the public, and identifying and avoiding problems—including potential significant effects—that may occur in later stages of project development.[109] Additionally, if agencies choose to consider additional alternatives and conduct clearer or more robust analyses, such analyses should improve societal outcomes by improving agency decision making. Because individual cases will vary, the magnitude of potential costs and benefits resulting from these proposed changes are difficult to anticipate, but CEQ has prepared a qualitative analysis in the accompanying regulatory impact analysis.

B. Regulatory Flexibility Act and Executive Order 13272, Proper Consideration of Small Entities in Agency Rulemaking

The Regulatory Flexibility Act (RFA), as amended, 5 U.S.C. 601 *et seq.,* and E.O. 13272, *Proper Consideration of Small Entities in Agency Rulemaking,*[110] require agencies to assess the impacts of proposed and final rules on small entities. Under the RFA, small entities include small businesses, small organizations, and small governmental jurisdictions. An agency must prepare an Initial Regulatory Flexibility Analysis unless it determines and certifies that a proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities. 5 U.S.C. 605(b). The proposed rule would not directly regulate small entities. Rather, the proposed rule would apply to Federal agencies and set forth the process for their compliance with NEPA. Accordingly, CEQ hereby certifies that the proposed rule, if promulgated, would not have a significant economic impact on a substantial number of small entities.

[106] Merriam-Webster, *https://www.merriam-webster.com/dictionary/appendix.*

[107] *Regulatory Planning and Review,* 58 FR 51735 (Oct. 4, 1993).

[108] E.O. 13563, *Improving Regulation and Regulatory Review,* 76 FR 3821 (Jan. 21, 2011).

[109] *See generally* Linda Luther, Cong. Rsch. Serv. R42479, The Role of the Environmental Review Process in Federally Funded Highway Projects: Background and Issues for Congress (2012), *https://crsreports.congress.gov/product/pdf/R/R42479.*

[110] 67 FR 53461 (Aug. 16, 2002).

C. National Environmental Policy Act

Under the CEQ regulations, major Federal actions may include regulations. When CEQ issued regulations in 1978, it prepared a ''special environmental assessment'' for illustrative purposes pursuant to E.O. 11991.[111] The NPRM for the 1978 rule stated ''the impacts of procedural regulations of this kind are not susceptible to detailed analysis beyond that set out in the assessment.'' [112] Similarly, in 1986, while CEQ stated in the final rule that there were ''substantial legal questions as to whether entities within the Executive Office of the President are required to prepare environmental assessments,'' it also prepared a special EA.[113] The special EA issued in 1986 supported a FONSI, and there was no finding made for the assessment of the 1978 final rule. CEQ also prepared a special EA and reached a FONSI for the Phase 1 rulemaking.

CEQ continues to take the position that a NEPA analysis is not required for establishing or updating NEPA procedures. *See Heartwood* v. *U.S. Forest Serv.,* 230 F.3d 947, 954–55 (7th Cir. 2000) (finding that neither NEPA or the CEQ regulations required the Forest Service to conduct an EA or an EIS prior to the promulgation of its procedures creating a CE). Nevertheless, based on past practice, CEQ has developed a special EA and has posted it in the docket. CEQ invites comments on the special EA.

D. Executive Order 13132, Federalism

E.O. 13132 requires agencies to develop an accountable process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.[114] Policies that have federalism implications include regulations that 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.[115] CEQ does not anticipate that this proposed rule has federalism implications because it applies to Federal agencies, not States.

E. Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

E.O. 13175 requires agencies to have a process to ensure meaningful and timely input by Tribal officials in the development of policies that have Tribal implications.[116] Such policies include regulations that have substantial direct effects on one or more Indian Tribes, on the relationship between the Federal Government and Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.[117] CEQ has assessed the impact of this proposed rule on Indian Tribal governments and has determined preliminarily that the proposed rule does significantly or uniquely affect these communities and seeks comment on this preliminary determination. CEQ engaged in government-to-government consultation with federally recognized Tribes on the Phase 2 rulemaking. As required by E.O. 13175, CEQ held a Tribal consultation on this rulemaking on November 12, 2021, and will be holding additional consultations during the public comment period.

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

E.O. 12898 requires agencies to make achieving environmental justice part of their missions by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on communities of color and low-income communities.[118] E.O. 14096 charges agencies to make achieving environmental justice part of its mission consistent with statutory authority by identifying, analyzing, and addressing disproportionate and adverse human health and environmental effects and hazards of Federal activities, including those related to climate change and cumulative impacts of environmental and other burdens on communities with environmental justice concerns.

CEQ has analyzed this proposed rule and preliminarily determined that it would not cause disproportionate and adverse human health or environmental effects on communities with environmental justice concerns. This rule would set forth implementing regulations for NEPA; it is in the agency implementation of NEPA when conducting reviews of proposed agency actions where consideration of environmental justice effects typically occurs. CEQ invites comment on this preliminary determination.

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

Agencies must prepare a Statement of Energy Effects for significant energy actions under E.O. 13211.[119] CEQ has preliminarily determined that this rulemaking is not a ''significant energy action'' because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy.

H. Executive Order 12988, Civil Justice Reform

Under section 3(a) of E.O. 12988, agencies must review their proposed regulations to eliminate drafting errors and ambiguities, draft them to minimize litigation, and provide a clear legal standard for affected conduct.[120] Section 3(b) provides a list of specific issues for review to conduct the reviews required by section 3(a).[121] CEQ has conducted this review and determined that this proposed rule complies with the requirements of E.O. 12988.

I. Unfunded Mandate Reform Act

Section 201 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531, requires Federal agencies to assess the effects of their regulatory actions on Tribal, State, and local governments, and the private sector to the extent that such regulations incorporate requirements specifically set forth in law. Before promulgating a rule that may result in the expenditure by a Tribal, State, or local government, in the aggregate, or by the private sector of $100 million, adjusted annually for inflation, in any 1 year, an agency must prepare a written statement that assesses the effects on Tribal, State, and local governments and the private sector. 2 U.S.C. 1532. This proposed rule would apply to Federal agencies and would not result in expenditures of $100 million or more for Tribal, State, and local governments, in the aggregate, or the private sector in any 1 year. This

[111] National Environmental Policy Act—Regulations: Proposed Implementation of Procedural Provisions, 43 FR 25230, 25232 (June 9, 1978); *see* E.O. 11991, *supra* note 26.

[112] National Environmental Policy Act—Regulations: Proposed Implementation of Procedural Provisions, *supra* note 111, at 25232.

[113] National Environmental Policy Act Regulations; Incomplete or Unavailable Information, *supra* note 29, at 15619.

[114] E.O. 13132, *Federalism,* 64 FR 43255 (Aug. 10, 1999).

[115] *Id.*

[116] E.O. 13175, *supra* note 53.

[117] *Id.*

[118] E.O. 12898, *supra* note 7.

[119] E.O. 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,* 66 FR 28355 (May 22, 2001).

[120] E.O. 12988, *Civil Justice Reform,* 61 FR 4729, 4731 (Feb. 7, 1996).

[121] *Id.*

proposed action also would not impose any enforceable duty, contain any unfunded mandate, or otherwise have any effect on small governments subject to the requirements of 2 U.S.C. 1531–1538.

J. Paperwork Reduction Act

This proposed rule would not impose any new information collection burden that would require additional review or approval by OMB under the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 40 CFR Parts 1500, 1501, 1502, 1503, 1504, 1505, 1506, 1507, and 1508

Administrative practice and procedure; Environmental impact statements; Environmental protection; Natural resources.

Brenda Mallory,
Chair.

For the reasons discussed in the preamble, the Council on Environmental Quality proposes to amend 40 CFR chapter V by revising subchapter A to read as follows:

■ 1. Revise subchapter A to read as follows:

PART 1500—PURPOSE AND POLICY

Sec.
1500.1 Purpose.
1500.2 Policy.
1500.3 NEPA compliance.
1500.4 Concise and informative environmental documents.
1500.5 Efficient process.
1500.6 Agency authority.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1501—NEPA AND AGENCY PLANNING

Sec.
1501.1 Purpose.
1501.2 Apply NEPA early in the process.
1501.3 Determine the appropriate level of NEPA review.
1501.4 Categorical exclusions.
1501.5 Environmental assessments.
1501.6 Findings of no significant impact.
1501.7 Lead agency.
1501.8 Cooperating agencies.
1501.9 Public and governmental engagement.
1501.10 Deadlines and schedule for the NEPA process.
1501.11 Programmatic environmental documents and tiering.
1501.12 Incorporation by reference into environmental documents.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1502—ENVIRONMENTAL IMPACT STATEMENT

Sec.
1502.1 Purpose of environmental impact statement.
1502.2 Implementation.
1502.3 Statutory requirements for environmental impact statements.
1502.4 Scoping.
1502.5 Timing.
1502.6 Interdisciplinary preparation.
1502.7 Page limits.
1502.8 Writing.
1502.9 Draft, final, and supplemental statements.
1502.10 Recommended format.
1502.11 Cover.
1502.12 Summary.
1502.13 Purpose and need.
1502.14 Alternatives including the proposed action.
1502.15 Affected environment.
1502.16 Environmental consequences.
1502.17 Summary of scoping information.
1502.18 List of preparers.
1502.19 Appendix.
1502.20 Publication of the environmental impact statement.
1502.21 Incomplete or unavailable information.
1502.22 Cost-benefit analysis.
1502.23 Methodology and scientific accuracy.
1502.24 Environmental review and consultation requirements.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1503—COMMENTING ON ENVIRONMENTAL IMPACT STATEMENTS

Sec.
1503.1 Inviting comments and requesting information and analyses.
1503.2 Duty to comment.
1503.3 Specificity of comments and information.
1503.4 Response to comments.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1504—PRE-DECISIONAL REFERRALS TO THE COUNCIL OF PROPOSED FEDERAL ACTIONS DETERMINED TO BE ENVIRONMENTALLY UNSATISFACTORY

Sec.
1504.1 Purpose.
1504.2 Early dispute resolution.
1504.3 Criteria and procedure for referrals and response.

PART 1505—NEPA AND AGENCY DECISION MAKING

Sec.
1505.1 [Reserved]
1505.2 Record of decision in cases requiring environmental impact statements.
1505.3 Implementing the decision.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1506—OTHER REQUIREMENTS OF NEPA

Sec.
1506.1 Limitations on actions during NEPA process.
1506.2 Elimination of duplication with State, Tribal, and local procedures.
1506.3 Adoption.
1506.4 Combining documents.
1506.5 Agency responsibility for environmental documents.
1506.6 [Reserved]
1506.7 Further guidance.
1506.8 Proposals for legislation.
1506.9 Filing requirements.
1506.10 Timing of agency action.
1506.11 Emergencies.
1506.12 Innovative approaches to NEPA reviews.
1506.13 Effective date.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1507—AGENCY COMPLIANCE

Sec.
1507.1 Compliance.
1507.2 Agency capability to comply.
1507.3 Agency NEPA procedures.
1507.4 Agency NEPA program information.

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1508—DEFINITIONS

Sec.
1508.1 Definitions.
1508.2 [Reserved]

Authority: 42 U.S.C. 4321–4347; 42 U.S.C. 4371–4375; 42 U.S.C. 7609; and E.O. 11514, 35 FR 4247, 3 CFR, 1966–1970, Comp., p. 902, as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1977 Comp., p. 123.

PART 1500—PURPOSE AND POLICY

§ 1500.1 Purpose.

(a) The National Environmental Policy Act (NEPA) is the basic national charter for protection of the environment. It establishes policy, sets goals (section 101), and provides direction (section 102) for carrying out the policy.

(1) Section 101(a) of NEPA establishes the national environmental policy of the Federal Government to use all practicable means and measures to foster and promote the general welfare, create and maintain conditions under which people and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations. Section 101(b) of NEPA establishes the continuing responsibility of the Federal Government to use all practicable means, consistent with other essential considerations of national policy, to help each generation serve as a trustee of the environment for succeeding generations; assure for all people safe, healthful, productive, and aesthetically and culturally pleasing surroundings; attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences; preserve important historic, cultural, and natural aspects of our national heritage, and maintain, wherever possible, an environment which supports diversity and variety of individual choice; achieve a balance between population and resource use which will permit high standards of living and a wide sharing of life's amenities; and enhance the quality of renewable resources and approach the maximum attainable recycling of depletable resources.

(2) Section 102(2) of NEPA establishes procedural requirements to carry out the policy and responsibilities established in section 101 of NEPA and contains ''action-forcing'' procedural provisions to ensure Federal agencies implement the letter and spirit of the Act. The purpose of the regulations in this subchapter is to set forth what Federal agencies must and should do to comply with the procedures and achieve the goals of the Act. The President, the Federal agencies, and the courts share responsibility for enforcing the Act so as to achieve the policy goals of section 101.

(b) Federal agency NEPA procedures must ensure that agencies identify, consider, and disclose to the public relevant environmental information early in the process before decisions are made and before actions are taken. The information should be of high quality, science-based, and accessible. Accurate scientific analysis, expert agency comments, and public scrutiny are essential to implementing NEPA. Most important, environmental documents must concentrate on the issues that are truly relevant to the action in question, rather than amassing needless detail. The regulations in this subchapter also are intended to ensure that Federal agencies conduct environmental reviews in a coordinated, consistent, predictable, and timely manner, and to reduce unnecessary burdens and delays. Finally, the regulations in this subchapter promote concurrent environmental reviews to ensure timely and efficient decision making.

(c) Ultimately, of course, it is not better documents but better decisions that count. NEPA's purpose is not to generate paperwork—even excellent paperwork—but to foster excellent action. The NEPA process is intended to help public officials make decisions that are based on an understanding of environmental consequences and take actions that protect, restore, and enhance the environment. The regulations in this subchapter provide the direction to achieve this purpose.

§ 1500.2 Policy.

Federal agencies shall to the fullest extent possible:

(a) Interpret and administer the policies, regulations, and public laws of the United States in accordance with the policies set forth in the Act and in these regulations.

(b) Implement procedures to make the NEPA process more useful to decision makers and the public; to reduce paperwork and the accumulation of extraneous background data; and to emphasize important environmental issues and alternatives. Environmental documents shall be concise, clear, and supported by evidence that agencies have conducted the necessary environmental analyses.

(c) Integrate the requirements of NEPA with other planning and environmental review procedures required by law or by agency practice so that all such procedures run concurrently rather than consecutively.

(d) Encourage and facilitate public engagement in decisions that affect the quality of the human environment, including meaningful engagement with communities with environmental justice concerns, which often include communities of color, low-income communities, indigenous communities, and Tribal communities.

(e) Use the NEPA process to identify and assess the reasonable alternatives to proposed actions that will avoid or minimize adverse effects of these actions upon the quality of the human environment, such as alternatives that will reduce climate change-related effects or address adverse health and environmental effects that disproportionately affect communities with environmental justice concerns.

(f) Use all practicable means, consistent with the requirements of the Act and other essential considerations of national policy, to restore and enhance the quality of the human environment and avoid or minimize any possible adverse effects of their actions upon the quality of the human environment.

§ 1500.3 NEPA compliance.

(a) *Mandate.* This subchapter is applicable to and binding on all Federal agencies for implementing the procedural provisions of the National Environmental Policy Act of 1969, as amended (Pub. L. 91–190, 42 U.S.C. 4321 *et seq.*) (NEPA or the Act). The regulations in this subchapter are issued pursuant to NEPA; the Environmental Quality Improvement Act of 1970, as amended (Pub. L. 91–224, 42 U.S.C. 4371 *et seq.*); and Executive Order 11514, Protection and Enhancement of Environmental Quality (March 5, 1970), as amended by Executive Order 11991, Relating to the Protection and Enhancement of Environmental Quality (May 24, 1977). The regulations in this subchapter apply to the whole of section 102(2) of NEPA. The provisions of the Act and the regulations in this subchapter must be read together as a whole to comply with the Act.

(b) *Review of NEPA compliance.* It is the Council's intention that judicial review of agency compliance with the regulations in this subchapter not occur before an agency has issued the record of decision or taken other final agency action, except with respect to claims brought by project sponsors related to deadlines under section 107(g)(3) of NEPA. It is also the Council's intention that minor, non-substantive errors that have no effect on agency decision making shall be considered harmless and shall not invalidate an agency action.

(c) *Severability.* The sections of this subchapter are separate and severable from one another. If any section or portion therein is stayed or determined to be invalid, or the applicability of any section to any person or entity is held invalid, it is the Council's intention that the validity of the remainder of those parts shall not be affected, with the remaining sections to continue in effect.

§ 1500.4 Concise and informative environmental documents.

Agencies shall prepare analytical, concise, and informative environmental documents by:

(a) Meeting appropriate page limits (§§ 1501.5(g) and 1502.7 of this subchapter).

(b) Discussing only briefly issues other than important ones (*e.g.,* § 1502.2(b) of this subchapter).

(c) Writing environmental documents in plain language (*e.g.,* § 1502.8 of this subchapter).

(d) Following a clear format for environmental impact statements (§ 1502.10 of this subchapter).

(e) Emphasizing the portions of the environmental document that are most useful to decision makers and the public (*e.g.,* §§ 1502.14, 1502.15, and 1502.16 of this subchapter) and reducing emphasis on background material (*e.g.,* § 1502.1 of this subchapter).

(f) Using the scoping process to identify important environmental issues deserving of study and to deemphasize unimportant issues, narrowing the scope of the environmental impact statement process (or, where an agency elects to do so, the environmental assessment process) accordingly (§§ 1501.9 and 1502.4 of this subchapter).

(g) Summarizing the environmental impact statement (§ 1502.12 of this subchapter).

(h) Using programmatic environmental documents and tiering from documents of broad scope to those of narrower scope, to eliminate repetitive discussions of the same issues (§ 1501.11 of this subchapter).

(i) Incorporating by reference (§ 1501.12 of this subchapter).

(j) Integrating NEPA requirements with other environmental review and consultation requirements (§ 1502.24 of this subchapter).

(k) Requiring that comments be as specific as possible (§ 1503.3 of this subchapter).

(*l*) Attaching and publishing only changes to the draft environmental impact statement, rather than rewriting and publishing the entire statement, when changes are minor (§ 1503.4(c) of this subchapter).

(m) Eliminating duplication with State, Tribal, and local procedures, by providing for joint preparation of environmental documents where practicable (§ 1506.2 of this subchapter), and with other Federal procedures, by providing that an agency may adopt appropriate environmental documents prepared by another Federal agency (§ 1506.3 of this subchapter).

(n) Combining environmental documents with other documents (§ 1506.4 of this subchapter).

§ 1500.5 Efficient process.

Agencies shall improve efficiency of their NEPA processes by:

(a) Using categorical exclusions to define categories of actions that normally do not have a significant effect on the human environment (§ 1501.4 of this subchapter) and therefore do not require preparation of an environmental assessment or environmental impact statement.

(b) Using a finding of no significant impact when an action not otherwise excluded will not have a significant effect on the human environment (§ 1501.6 of this subchapter) and therefore does not require preparation of an environmental impact statement.

(c) Integrating the NEPA process into early planning (§ 1501.2 of this subchapter).

(d) Engaging in interagency cooperation before or during the preparation of an environmental assessment or environmental impact statement, rather than waiting to submit comments on a completed document (§§ 1501.7 and 1501.8 of this subchapter).

(e) Ensuring the swift and fair resolution of lead agency disputes (§ 1501.7 of this subchapter).

(f) Using the scoping process for early identification of the important issues that require detailed analysis (§ 1502.4 of this subchapter).

(g) Meeting appropriate deadlines for the environmental assessment and environmental impact statement processes (§ 1501.10 of this subchapter).

(h) Preparing environmental documents early in the process (§ 1502.5 and § 1501.5(d) of this subchapter).

(i) Integrating NEPA requirements with other environmental review and consultation requirements (§ 1502.24 of this subchapter).

(j) Eliminating duplication with State, Tribal, and local procedures by providing for joint preparation of environmental documents where practicable (§ 1506.2 of this subchapter) and with other Federal procedures by providing that agencies may jointly prepare or adopt appropriate environmental documents prepared by another agency (§ 1506.3 of this subchapter).

(k) Combining environmental documents with other documents (§ 1506.4 of this subchapter).

(*l*) Using accelerated procedures for proposals for legislation (§ 1506.8 of this subchapter).

§ 1500.6 Agency authority.

Each agency shall interpret the provisions of the Act as a supplement to its existing authority and as a mandate to view policies and missions in the light of the Act's national environmental objectives, to the extent consistent with its existing authority. Agencies shall review their policies, procedures, and regulations accordingly and revise them as necessary to ensure full compliance with the purposes and provisions of the Act and the regulations in this subchapter. The phrase ''to the fullest extent possible'' in section 102 of NEPA means that each agency of the Federal Government shall comply with that section unless an agency activity, decision, or action is exempted from NEPA by law or compliance with NEPA is impossible.

PART 1501—NEPA AND AGENCY PLANNING

§ 1501.1 Purpose.

The purposes of this part include:

(a) Integrating the NEPA process into agency planning at an early stage to facilitate appropriate consideration of NEPA's policies, promote an efficient process, and reduce delay.

(b) Providing for early engagement in the environmental review process with other agencies, State, Tribal, and local governments, and affected or interested persons, entities, and communities before a decision is made.

(c) Providing for the swift and fair resolution of interagency disputes.

(d) Identifying at an early stage the important environmental issues deserving of study, and deemphasizing unimportant issues, narrowing the scope of the environmental review and enhancing efficiency accordingly.

(e) Promoting accountability by establishing appropriate deadlines and requiring schedules.

§ 1501.2 Apply NEPA early in the process.

(a) Agencies should integrate the NEPA process with other planning and authorization processes at the earliest reasonable time to ensure that agencies consider environmental impacts in their planning and decisions, to avoid delays later in the process, and to head off potential conflicts.

(b) Each agency shall:

(1) Comply with the mandate of section 102(2)(A) of NEPA to utilize a systematic, interdisciplinary approach, which will ensure the integrated use of the natural and social sciences and the environmental design arts in planning and in decision making that may have an impact on the human environment, as specified by § 1507.2(a) of this subchapter.

(2) Identify environmental effects and values in adequate detail so the decision maker can appropriately consider such effects and values alongside economic and technical analyses. Whenever practicable, agencies shall review and publish environmental documents and appropriate analyses at the same time as other planning documents.

(3) Study, develop, and describe appropriate alternatives to recommended courses of action in any proposal that involves unresolved conflicts concerning alternative uses of available resources, as provided by section 102(2)(H) of NEPA.

(4) Provide for actions subject to NEPA that are planned by applicants or other non-Federal entities before Federal involvement so that:

(i) Policies or designated staff are available to advise potential applicants of studies or other information foreseeably required for later Federal action.

(ii) The Federal agency consults early with appropriate State, Tribal, and local governments and with interested individuals and organizations when their involvement is reasonably foreseeable.

(iii) The Federal agency commences its NEPA process at the earliest reasonable time (§§ 1501.5(d) and 1502.5(b) of this subchapter).

§ 1501.3 Determine the appropriate level of NEPA review.

(a) *Applicability.* As a threshold determination, an agency shall assess whether NEPA applies to the proposed activity or decision. In assessing whether NEPA applies, Federal agencies should determine:

(1) Whether the proposed activity or decision is exempted from NEPA by law;

(2) Whether compliance with NEPA would clearly and fundamentally conflict with the requirements of another provision of law;

(3) Whether statutory provisions applicable to the agency's proposed activity or decision make compliance with NEPA impossible; and

(4) Whether the proposed activity or decision is a major Federal action, including whether:

(i) The proposed activity or decision is a final agency action within the meaning of such term in chapter 5 of title 5, United States Code (§ 1508.1(u)(2)(viii)); or

(ii) The proposed activity or decision is a non-discretionary action with respect to which such agency does not have authority to take environmental factors into consideration in determining whether to take the proposed action (§ 1508.1(u)(2)(vi)).

(b) *Scope of action and analysis.* If the agency determines that NEPA applies, the agency shall consider the scope of the proposed action and its potential effects to inform the agency's determination of the appropriate level of NEPA review. The agency shall evaluate, in a single review, proposals or parts of proposals that are related closely enough to be, in effect, a single course of action. The agency also shall consider whether there are connected actions, which are closely related Federal activities or decisions that should be considered in the same NEPA review that:

(1) Automatically trigger other actions that may require NEPA review;

(2) Cannot or will not proceed unless other actions are taken previously or simultaneously; or

(3) Are interdependent parts of a larger action and depend on the larger action for their justification.

(c) *Levels of NEPA review.* In assessing the appropriate level of NEPA review, agencies may make use of any reliable data source and are not required to undertake new scientific or technical research unless it is essential to a reasoned choice among alternatives, and the overall costs and timeframe of obtaining it are not unreasonable. Agencies should determine whether the proposed action:

(1) Normally does not have significant effects and is categorically excluded (§ 1501.4);

(2) Is not likely to have significant effects or the significance of the effects is unknown and is therefore appropriate for an environmental assessment (§ 1501.5); or

(3) Is likely to have significant effects and is therefore appropriate for an environmental impact statement (part 1502 of this subchapter).

(d) *Significance determination—context and intensity.* In considering whether the effects of the proposed action are significant, agencies shall examine both the context of an action and the intensity of the effects.

(1) Agencies shall analyze the significance of an action in several contexts. Agencies should consider the characteristics of the relevant geographic area, such as proximity to unique or sensitive resources or vulnerable communities. Depending on the scope of the action, agencies should consider the potential global, national, regional, and local contexts as well as the duration, including short-and long-term effects.

(2) Agencies shall analyze the intensity of effects considering the following factors, as applicable and in relationship to one another:

(i) Effects may be beneficial or adverse. However, only actions with significant adverse effects require an environmental impact statement. A significant adverse effect may exist even if the agency considers that on balance the effects of the action will be beneficial. Agencies should consider the duration of effects; for instance, a proposed action may have short-term adverse effects but long-term beneficial effects.

(ii) The degree to which the proposed action may adversely affect public health and safety.

(iii) The degree to which the proposed action may adversely affect unique characteristics of the geographic area such as historic or cultural resources, park lands, Tribal sacred sites, prime farmlands, wetlands, wild and scenic rivers, or ecologically critical areas.

(iv) Whether the action may violate relevant Federal, State, Tribal, or local laws or other requirements or be inconsistent with Federal, State, Tribal, or local policies designed for the protection of the environment.

(v) The degree to which the potential effects on the human environment are highly uncertain.

(vi) The degree to which the action may relate to other actions with adverse environmental effects, including actions that are individually insignificant but significant in the aggregate. Significance cannot be avoided by terming an action temporary that is not temporary in fact or by segmenting it into small component parts.

(vii) The degree to which the action may adversely affect resources listed or eligible for listing in the National Register of Historic Places.

(viii) The degree to which the action may adversely affect an endangered or threatened species or its habitat, including habitat that has been determined to be critical under the Endangered Species Act of 1973.

(ix) The degree to which the action may have disproportionate and adverse effects on communities with environmental justice concerns.

(x) The degree to which the action may adversely affect rights of Tribal Nations that have been reserved through treaties, statutes, or Executive Orders.

§ 1501.4 Categorical exclusions.

(a) For efficiency and consistent with § 1507.3(c)(8)(ii) of this subchapter, agencies shall establish categorical exclusions for categories of actions that normally do not have a significant effect on the human environment, individually or in the aggregate, and therefore do not require preparation of an environmental assessment or environmental impact statement unless extraordinary circumstances exist that make application of the categorical exclusion inappropriate, consistent with paragraph (b) of this section. Agencies may establish categorical exclusions individually or jointly with other agencies.

(b) If an agency determines that a categorical exclusion identified in its agency NEPA procedures covers a proposed action, the agency shall evaluate the action for extraordinary circumstances in which a normally excluded action may have a significant effect.

(1) If an extraordinary circumstance exists, the agency nevertheless may apply the categorical exclusion if the agency conducts an analysis and determines that the proposed action does not in fact have the potential to result in significant effects notwithstanding the extraordinary circumstance or the agency modifies the action to address the extraordinary circumstance. In such cases, the agency shall document such determination and should publish it on the agency's website or otherwise make it publicly available.

(2) If the agency cannot categorically exclude the proposed action, the agency shall prepare an environmental assessment or environmental impact statement, as appropriate.

(c) In addition to the process for establishing categorical exclusions under § 1507.3(c)(8) of this subchapter, agencies may establish categorical exclusions through a land use plan, a decision document supported by a programmatic environmental impact statement or programmatic environmental assessment, or other equivalent planning or programmatic decision, so long as the agency:

(1) Provides the Council an opportunity to review and comment prior to public comment;

(2) Provides notification and an opportunity for public comment;

(3) Substantiates its determination that the category of actions normally does not have significant effects, individually or in the aggregate;

(4) Identifies extraordinary circumstances;

(5) Establishes a process for determining that a categorical exclusion applies to a specific action or actions in the absence of extraordinary circumstances, or, where extraordinary circumstances are present, for determining the agency may apply the categorical exclusion consistent with (b)(1) of this section; and

(6) Publishes a list of all categorical exclusions established through these mechanisms on its website.

(d) Categorical exclusions established consistent with paragraph (c) of this section or § 1507.3(c)(8) may:

(1) Cover specific geographic areas or areas that share common characteristics, *e.g.,* habitat type;

(2) Have a limited duration;

(3) Include mitigation measures that, in the absence of extraordinary circumstances, will ensure that any environmental effects are not significant, so long as a process is established for monitoring and enforcing any required mitigation measures, including through the suspension or revocation of the relevant agency action; or

(4) Provide criteria that would cause the categorical exclusion to expire because the agency's determination that the category of action does not have significant effects, individually or in the aggregate, is no longer applicable, including, as appropriate, because:

(i) The number of individual actions covered by the categorical exclusion exceeds a specific threshold;

(ii) Individual actions covered by the categorical exclusion are too close to one another in proximity or time; or

(iii) Environmental conditions or information upon which the agency's determination was based have changed.

(e) An agency may apply a categorical exclusion listed in another agency's NEPA procedures to a proposed action or a category of proposed actions consistent with this paragraph. The agency shall:

(1) Identify the categorical exclusion listed in another agency's NEPA procedures that covers its proposed action or a category of proposed actions;

(2) Consult with the agency that established the categorical exclusion to ensure that the proposed application of the categorical exclusion is appropriate;

(3) Evaluate the proposed action or category of proposed actions for extraordinary circumstances, consistent with paragraph (b) of this section;

(4) Provide public notice of the categorical exclusion that the agency plans to use for the proposed action or category of proposed actions; and

(5) Publish the documentation of the application of the categorical exclusion.

§ 1501.5 Environmental assessments.

(a) An agency shall prepare an environmental assessment for a proposed action that is not likely to have significant effects or when the significance of the effects is unknown unless the agency finds that a categorical exclusion (§ 1501.4) is applicable or has decided to prepare an environmental impact statement.

(b) An agency may prepare an environmental assessment on any action to assist agency planning and decision making.

(c) An environmental assessment shall:

(1) Briefly provide sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact;

(2) Briefly discuss the:

(i) Purpose and need for the proposed agency action;

(ii) Alternatives as required by section 102(2)(H) of NEPA; and

(iii) Environmental effects of the proposed action and alternatives;

(3) List the Federal agencies; State, Tribal, and local governments and agencies; or persons consulted; and

(4) Provide a unique identification number for tracking purposes, which the agency shall reference on all associated environmental review documents prepared for the proposed action.

(d) For applications to the agency requiring an environmental assessment, the agency shall commence the environmental assessment as soon as practicable after receiving the application.

(e) If an agency publishes a draft environmental assessment, the agency shall invite public comment and consider those comments in preparing the final environmental assessment.

(f) Agencies shall involve the public, State, Tribal, and local governments, relevant agencies, and any applicants, to the extent practicable in preparing environmental assessments (*see* § 1501.9).

(g) The text of an environmental assessment shall not exceed 75 pages, not including any citations or appendices.

(h) Agencies may supplement environmental assessments if a major Federal action remains to occur, and the agency determines supplementation is appropriate. Agencies may reevaluate an environmental assessment or otherwise document a finding that changes to the proposed action or new circumstances or information relevant to environmental concerns are not substantial, or the underlying assumptions of the analysis remain valid.

(i) Agencies generally should apply the provisions of §§ 1502.21 and 1502.23 to environmental assessments.

(j) As appropriate to improve efficiency and effectiveness of environmental assessments, agencies may apply the other provisions of part 1502 and 1503 of this subchapter, including §§ 1502.4, 1502.22, 1502.24, and 1503.4, to environmental assessments.

§ 1501.6 Findings of no significant impact.

(a) An agency shall prepare a finding of no significant impact if the agency determines, based on the environmental

assessment, not to prepare an environmental impact statement because the proposed action will not have significant effects, or a mitigated finding of no significant impact because the proposed action will not have significant effects due to mitigation.

(1) The agency shall make the finding of no significant impact available to the affected public as specified in § 1501.9(d)(2) of this subchapter.

(2) In the following circumstances, the agency shall make the finding of no significant impact available for public review for 30 days before the agency makes its final determination whether to prepare an environmental impact statement and before the action may begin:

(i) The proposed action is or is closely similar to one that normally requires the preparation of an environmental impact statement under the procedures adopted by the agency pursuant to § 1507.3 of this subchapter; or

(ii) The nature of the proposed action is one without precedent.

(b) The finding of no significant impact shall include the environmental assessment or incorporate it by reference and shall note any other environmental documents related to it (§ 1502.4(d)(3)). If the environmental assessment is included, the finding need not repeat any of the discussion in the assessment but may incorporate it by reference.

(c) The finding of no significant impact shall state the authority for any mitigation that the agency has adopted and any applicable monitoring or enforcement provisions. If the agency finds no significant effects based on mitigation, the mitigated finding of no significant impact shall state the enforceable mitigation requirements or commitments that will be undertaken and the authority to enforce them, such as permit conditions, agreements, or other measures. In addition, the agency shall prepare a monitoring and compliance plan for any mitigation the agency relies on as a component of the proposed action consistent with § 1505.3(c) of this subchapter.

§ 1501.7 Lead agency.

(a) A lead agency shall supervise the preparation of an environmental impact statement or environmental assessment if more than one Federal agency either:

(1) Proposes or is involved in the same action; or

(2) Is involved in a group of actions directly related to each other because of their functional interdependence or geographical proximity.

(b) Federal, State, Tribal, or local agencies may serve as a joint lead agency to prepare an environmental impact statement or environmental assessment (§ 1506.2 of this subchapter). A joint lead agency shall jointly fulfill the role of a lead agency.

(c) If an action falls within the provisions of paragraph (a) of this section, the participating Federal agencies shall determine, by letter or memorandum, which agencies will be lead or joint lead agencies, and the lead agency shall determine which agencies will be cooperating agencies. The agencies shall resolve the lead agency question so as not to cause delay. If there is disagreement among the agencies, the following factors (which are listed in order of descending importance) shall determine lead agency designation:

(1) Magnitude of agency's involvement;

(2) Project approval or disapproval authority;

(3) Expertise concerning the action's environmental effects;

(4) Duration of agency's involvement; and

(5) Sequence of agency's involvement.

(d) Any Federal, State, Tribal, or local agency or individual substantially affected by the absence of a lead agency designation, may make a written request to the senior agency officials of the potential lead agencies that a lead agency be designated. An agency that receives a request under this paragraph shall transmit such request to each participating Federal agency and to the Council.

(e) If Federal agencies are unable to agree on which agency will be the lead agency or if the procedure described in paragraph (c) of this section has not resulted in a lead agency designation within 45 days of the written request to the senior agency officials, any of the agencies or individuals concerned may file a request with the Council asking it to determine which Federal agency shall be the lead agency. The Council shall transmit a copy of the request to each potential lead agency. The request shall consist of:

(1) A precise description of the nature and extent of the proposed action; and

(2) A detailed statement of why each potential lead agency should or should not be the lead agency under the criteria specified in paragraph (c) of this section.

(f) Any potential lead agency may file a response no later than 20 days after a request is filed with the Council. As soon as possible, but not later than 40 days after receiving the request and all responses to it, the Council shall designate which Federal agency will be the lead agency and which other Federal agencies will be cooperating agencies.

(g) To the extent practicable, if a proposal will require action by more than one Federal agency and the lead agency determines that it requires preparation of an environmental impact statement, the lead and cooperating agencies shall evaluate the proposal in a single environmental impact statement and shall issue, except where inappropriate or inefficient, a joint record of decision. To the extent practicable, if a proposal will require action by more than one Federal agency and the lead agency determines that it requires preparation of an environmental assessment, the lead and cooperating agencies shall evaluate the proposal in a single environmental assessment and issue a joint finding of no significant impact or jointly determine to prepare an environmental impact statement.

(h) With respect to cooperating agencies, the lead agency shall:

(1) Request the participation of each cooperating agency in the NEPA process at the earliest practicable time;

(2) Consider any analysis or proposal created by a cooperating agency and, to the maximum extent practicable, use the environmental analysis and information provided by cooperating agencies;

(3) Meet with a cooperating agency at the latter's request; and

(4) Determine the purpose and need, and alternatives in consultation with any cooperating agency.

§ 1501.8 Cooperating agencies.

(a) The purpose of this section is to emphasize agency cooperation early in the NEPA process. Upon request of the lead agency, any Federal agency with jurisdiction by law shall be a cooperating agency. In addition, upon request of the lead agency, any other Federal agency with special expertise with respect to any environmental issue may be a cooperating agency. A State, Tribal, or local agency of similar qualifications may become a cooperating agency by agreement with the lead agency. Relevant special expertise may include Indigenous Knowledge. An agency may request that the lead agency designate it a cooperating agency, and a Federal agency may appeal a denial of its request to the Council, in accordance with § 1501.7(e).

(b) Each cooperating agency shall:

(1) Participate in the NEPA process at the earliest practicable time.

(2) Participate in the scoping process (described in § 1502.4).

(3) On request of the lead agency, assume responsibility for developing

information and preparing environmental analyses, including portions of the environmental impact statement or environmental assessment concerning which the cooperating agency has special expertise.

(4) On request of the lead agency, make available staff support to enhance the lead agency's interdisciplinary capability.

(5) Normally use its own funds. To the extent available funds permit, the lead agency shall fund those major activities or analyses it requests from cooperating agencies. Potential lead agencies shall include such funding requirements in their budget requests.

(6) Consult with the lead agency in developing the schedule (§ 1501.10), meet the schedule, and elevate, as soon as practicable, to the senior agency official of the lead agency any issues relating to purpose and need, alternatives, or other issues that may affect any agencies' ability to meet the schedule.

(7) Meet the lead agency's schedule for providing comments.

(8) To the maximum extent practicable, jointly issue environmental documents with the lead agency.

(c) In response to a lead agency's request for assistance in preparing the environmental documents (described in paragraph (b)(3), (4), or (5) of this section), a cooperating agency may reply that other program commitments preclude any involvement or the degree of involvement requested in the action that is the subject of the environmental impact statement or environmental assessment. The cooperating agency shall submit a copy of this reply to the Council and the senior agency official of the lead agency.

§ 1501.9 Public and governmental engagement.

(a) *Purpose.* Agencies conduct public engagement to inform the public of an agency's proposed action, allow for meaningful engagement during the NEPA process, and ensure decision makers are informed by the views of the public. Agencies conduct governmental engagement to identify the potentially affected Federal, State, Tribal, and local governments, invite them to serve as cooperating agencies, as appropriate, and ensure that participating agencies have opportunities to engage in the environmental review process, as appropriate.

(b) *Responsibility.* Agencies shall determine the appropriate methods of public and governmental engagement. For environmental impact statements, in addition to the requirements of this section, agencies also shall comply with the requirements for scoping set forth in § 1502.4 of this subchapter.

(c) *Outreach.* The lead agency should:

(1) Invite the participation of likely affected Federal, State, Tribal, and local agencies and governments, as early as practicable, including, as appropriate, as cooperating agencies under § 1501.8 of this subchapter;

(2) Conduct early engagement with likely affected or interested members of the public (including those who might not be in accord with the action), unless there is a limited exception under § 1507.3(d)(3) of this subchapter; and

(3) Consider what methods of outreach and notification are necessary and appropriate based on the likely affected entities; the scope, scale, and complexity of the proposed action and alternatives; the degree of public interest; and other relevant factors. When selecting appropriate methods for providing public notification, agencies shall consider the ability of affected persons and agencies to access electronic media and the primary language of affected persons.

(d) *Notification.* Agencies shall:

(1) Publish notification of proposed actions they are analyzing through an environmental impact statement.

(2) Provide public notification of NEPA-related hearings, public meetings, and other opportunities for public engagement, and, as appropriate, the availability of environmental documents to inform those persons and agencies who may be interested or affected by their proposed actions.

(i) In all cases, the agency shall notify those who have requested notification on an individual action.

(ii) In the case of an action with effects of national concern, notice shall include publication in the **Federal Register.** An agency also may notify entities and persons who have requested regular notification.

(iii) In the case of an action with effects primarily of local concern, the notification may include distribution to or through:

(A) State, Tribal, and local governments and agencies that may be interested or affected by the proposed action.

(B) Following the affected State or Tribe's public notification procedures for comparable actions.

(C) Publication in local newspapers having general circulation.

(D) Other local media.

(E) Potentially interested community organizations including small business associations.

(F) Publication in newsletters that may be expected to reach potentially interested persons.

(G) Direct mailing to owners and occupants of nearby or affected property.

(H) Posting of notification on- and off-site in the area where the action is to be located.

(I) Electronic media (*e.g.,* a project or agency website, dashboard, email list, or social media). Agencies should establish email notification lists or similar methods for the public to easily request electronic notifications for a proposed action.

(3) Make environmental impact statements, the comments received, and any underlying documents available to the public pursuant to the provisions of the Freedom of Information Act, as amended (5 U.S.C. 552).

(e) *Public meetings and hearings.* Agencies may hold or sponsor public hearings, public meetings, or other opportunities for public engagement whenever appropriate or in accordance with statutory or regulatory requirements or applicable agency NEPA procedures. Agencies may conduct public hearings and public meetings by means of electronic communication except where another format is required by law. When determining the format for a public hearing or public meeting, agencies should consider the needs of affected communities. When accepting comments for electronic or virtual public hearings or meetings, agencies shall allow the public to submit comments electronically, by regular mail, or by other appropriate methods.

(f) *Agency procedures.* Agencies shall make diligent efforts to engage the public in preparing and implementing their NEPA procedures (§ 1507.3 of this subchapter).

§ 1501.10 Deadlines and schedule for the NEPA process.

(a) To ensure that agencies conduct sound NEPA reviews as efficiently and expeditiously as practicable, Federal agencies shall set deadlines and schedules appropriate to individual actions or types of actions consistent with this section and the time intervals required by § 1506.10 of this subchapter. Where applicable, the lead agency shall establish the schedule and make any necessary updates to the schedule in consultation with and seek the concurrence of joint lead, cooperating, and participating agencies, and in consultation with project sponsors or applicants.

(b) To ensure timely decision making, agencies shall complete:

(1) Environmental assessments within 1 year, unless the lead agency extends the deadline in writing and in

consultation with any applicant or project sponsor, and establishes a new deadline that provides only so much additional time as is necessary to complete the environmental assessment.

(2) Environmental impact statements within 2 years, unless the lead agency extends the deadline in writing and in consultation with any applicant or project sponsor and establishes a new deadline that provides only so much additional time as is necessary to complete the environmental impact statement.

(3) The deadlines in paragraphs (b)(1) and (b)(2) of this section are measured from the sooner of, as applicable:

(i) the date on which the agency determines that NEPA requires an environmental impact statement or environmental assessment for the proposed action;

(ii) the date on which the agency notifies an applicant that the application to establish a right-of-way for the proposed action is complete; and

(iii) the date on which the agency issues a notice of intent for the proposed action.

(4) The lead agency shall annually submit the report to Congress on missed deadlines for environmental assessments and environmental impact statements required by section 107(h) of NEPA.

(c) To facilitate predictability, the lead agency shall develop a schedule for completion of environmental impact statements and environmental assessments as well as any authorizations required to carry out the action. The lead agency shall set milestones for all environmental reviews, permits, and authorizations required for implementation of the action, in consultation with any project sponsor or applicant and in consultation with and seek the concurrence of all joint lead, cooperating, and participating agencies, as soon as practicable. Schedules may vary depending on the type of action and in consideration of other factors in paragraph (d). The lead agency should develop a schedule that is based on its expertise reviewing similar types of actions under NEPA. If the lead agency or any participating agency anticipates that a milestone, including those for a review, permit, or authorization, will not be completed, it shall notify the agency responsible for the milestone or issuance of the review, permit, or authorization and the lead agency, as applicable, and request that they take appropriate measures to comply with the schedule. As soon as practicable, the lead and any other agency affected by a potentially missed milestone shall elevate any unresolved disputes contributing to the missed milestone to the appropriate officials of the agencies responsible for the missed milestone, to ensure timely resolution within the deadlines for the individual action.

(d) The lead agency may consider the following factors in determining the schedule and deadlines:

(1) Potential for environmental harm.

(2) Size of the proposed action.

(3) State of the art of analytic techniques.

(4) Degree of public need for the proposed action, including the consequences of delay.

(5) Number of persons and agencies affected.

(6) Availability of relevant information.

(7) Degree to which a substantial dispute exists as to the size, location, nature, or consequences of the proposed action and its effects.

(8) Time limits imposed on the agency by law, regulation, or Executive Order.

(e) The schedule for environmental impact statements shall include the following milestones:

(1) The publication of the notice of intent;

(2) The issuance of the draft environmental impact statement;

(3) The public comment period on the draft environmental impact statement, consistent with § 1506.10 of this subchapter;

(4) The issuance of the final environmental impact statement; and

(5) The issuance of the record of decision.

(f) The schedule for environmental assessments shall include the following milestones:

(1) Decision to prepare an environmental assessment;

(2) Issuance of the draft environmental assessment, where applicable;

(3) The public comment period on the draft environmental assessment, consistent with § 1501.5 of this subchapter, where applicable; and

(4) Issuance of the final environmental assessment and decision on whether to issue a finding of no significant impact or issue a notice of intent to prepare an environmental impact statement.

(g) An agency may designate a person (such as the project manager or a person in the agency's office with NEPA responsibilities) to expedite the NEPA process.

(h) For environmental impact statements, agencies shall make schedules for completing the NEPA process publicly available, such as on their website or another publicly accessible platform. If agencies make subsequent changes to the schedule, agencies shall publish revisions to the schedule and explain the basis for substantial changes.

§ 1501.11 Programmatic environmental documents and tiering.

(a) *Programmatic environmental document.* Agencies may prepare programmatic environmental documents, which may be either environmental impact statements or environmental assessments, to evaluate the environmental effects of policies, programs, plans, or groups of related activities. When agencies prepare such documents, they should be relevant to the agency decisions and timed to coincide with meaningful points in agency planning and decision making. Agencies may use programmatic environmental documents to conduct a broad or holistic evaluation of effects or policy alternatives; evaluate widely applicable measures; or avoid duplicative analysis for individual actions by first considering relevant issues at a broad or programmatic level.

(1) When preparing programmatic environmental documents (including proposals by more than one agency), agencies may find it useful to evaluate the proposal(s) in one of the following ways:

(i) Geographically, including actions occurring in the same general location, such as body of water, region, or metropolitan area.

(ii) Thematically or by sector, including actions that have relevant similarities, such as common timing, impacts, alternatives, methods of implementation, technology, media, or subject matter.

(iii) By stage of technological development, including Federal or federally assisted research, development, or demonstration programs for new technologies that, if applied, could significantly affect the quality of the human environment. Documents on such programs should be completed before the program has reached a stage of investment or commitment to implementation likely to determine subsequent development or restrict later alternatives.

(2) Agency actions that may be appropriate for programmatic documents include:

(i) Programs, policies, or plans, including land use or resource management plans;

(ii) Regulations;

(iii) National or regional actions;

(iv) Actions that have multiple stages or phases, and are part of an overall plan or program; or

(v) A group of projects or related types of projects.

(3) Agencies should, as appropriate, employ scoping (§ 1502.4 of this subchapter), tiering (paragraph (b) of this section), and other methods listed in §§ 1500.4 and 1500.5 of this subchapter, to describe the relationship between the programmatic document and related individual actions and to avoid duplication and delay.

(b) *Tiering.* Where an existing environmental impact statement, environmental assessment, or programmatic environmental document is relevant to a later proposed action, agencies may employ tiering. Tiering allows subsequent tiered environmental analysis to avoid duplication and focus on issues, effects, or alternatives not fully addressed in a programmatic document, environmental impact statement, or environmental assessment prepared at an earlier phase or stage. Agencies generally should tier their environmental impact statements and environmental assessments when it would eliminate repetitive discussions of the same issues, focus on the actual issues ripe for decision, and exclude from consideration issues already decided.

(1) When an agency has prepared a programmatic environmental review or other environmental impact statement or environmental assessment for a program or policy and then prepares a subsequent statement or assessment on an action included within the program or policy (such as a project- or site-specific action), the tiered document shall discuss the relationship between the tiered document and the previous review, and summarize and incorporate by reference the issues discussed in the broader document. The tiered document shall concentrate on the issues specific to the subsequent action, analyzing site-, phase-, or stage-specific conditions and reasonably foreseeable effects. The agency shall provide for public engagement opportunities consistent with the type of environmental document prepared and appropriate for the location, phase, or stage. The tiered document shall state where the earlier document is publicly available.

(2) Tiering is appropriate when the sequence from an environmental impact statement or environmental assessment is:

(i) From a programmatic, plan, or policy environmental impact statement or environmental assessment to a program, plan, or policy statement or assessment of lesser or narrower scope or to a site-specific statement or assessment.

(ii) From an environmental impact statement or environmental assessment on a specific action at an early stage (such as need and site selection) to a supplement (which is preferred) or a subsequent statement or assessment at a later stage (such as environmental mitigation). Tiering in such cases is appropriate when it helps the agency to focus on the issues that are ripe for decision and exclude from consideration issues already decided or not yet ripe.

(c) When an agency prepares a programmatic environmental document for which judicial review was available, the agency may rely on the analysis included in the programmatic environmental document in a subsequent environmental document for related actions as follows:

(1) Within 5 years and without additional review of the analysis in the programmatic environmental document, unless there are substantial new circumstances or information about the significance of adverse effects that bear on the analysis; or

(2) After 5 years, so long as the agency reevaluates the analysis in the programmatic environmental document and any underlying assumption to ensure reliance on the analysis remains valid. The agency shall briefly document its reevaluation and explain why the analysis remains valid considering any new and substantial information or circumstances.

§ 1501.12 Incorporation by reference into environmental documents.

Agencies shall incorporate material, such as planning studies, analyses, or other relevant information, into environmental documents by reference when the effect will be to cut down on bulk without impeding agency and public review of the action. Agencies shall cite the incorporated material in the document, briefly describe its content, and briefly explain the relevance of the incorporated material to the environmental document. Agencies shall not incorporate material by reference unless it is reasonably available for inspection, such as on a publicly accessible website, by potentially interested persons within the time allowed for comment. Agencies should provide digital references, such as hyperlinks, to the incorporated material or otherwise indicate how the public can access the material for inspection. Agencies shall not incorporate by reference material based on proprietary data that is not available for review and comment.

PART 1502—ENVIRONMENTAL IMPACT STATEMENT

§ 1502.1 Purpose of environmental impact statement.

(a) The primary purpose of an environmental impact statement prepared pursuant to section 102(2)(C) of NEPA is to serve as an action-forcing device by ensuring agencies consider the environmental effects of their action in decision making, so that the policies and goals defined in the Act are infused into the ongoing programs and actions of the Federal Government.

(b) Environmental impact statements shall provide full and fair discussion of significant effects and shall inform decision makers and the public of reasonable alternatives that would avoid or minimize adverse effects or enhance the quality of the human environment. Agencies shall focus on important environmental issues and reasonable alternatives and shall reduce paperwork and the accumulation of extraneous background data.

(c) Environmental impact statements shall be concise, clear, and to the point, and shall be supported by evidence that the agency has made the necessary environmental analyses. An environmental impact statement is more than a disclosure document. Federal agencies shall use environmental impact statements in conjunction with other relevant material to plan actions and make decisions.

§ 1502.2 Implementation.

To achieve the purposes set forth in § 1502.1 agencies shall prepare environmental impact statements in the following manner:

(a) Environmental impact statements shall not be encyclopedic.

(b) Environmental impact statements shall discuss effects in proportion to their significance. There shall be only brief discussion of other than important issues. As in an environmental assessment and finding of no significant impact, there should be only enough discussion to show why more study is not warranted.

(c) Environmental impact statements shall be analytical, concise, and no longer than necessary to comply with NEPA and with the regulations in this subchapter. Length should be proportional to potential environmental effects and the scope and complexity of the action.

(d) Environmental impact statements shall state how alternatives considered in them and decisions based on them will or will not achieve the requirements of sections 101 and 102(1) of NEPA, the regulations in this

subchapter, and other environmental laws and policies.

(e) The range of alternatives discussed in environmental impact statements shall encompass those to be considered by the decision maker.

(f) Agencies shall not commit resources prejudicing the selection of alternatives before making a decision (*see also* § 1506.1 of this subchapter).

(g) Environmental impact statements shall serve as the means of assessing the environmental impact of proposed agency actions, rather than justifying decisions already made.

§ 1502.3 Statutory requirements for environmental impact statements.

As required by section 102(2)(C) of NEPA, environmental impact statements are to be included in every Federal agency recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment.

§ 1502.4 Scoping.

(a) *Generally.* Agencies shall use an early and open process, consistent with § 1501.9 of this subchapter, to determine the scope of issues for analysis in an environmental impact statement, including identifying the important issues and eliminating from further study unimportant issues. Scoping may begin as soon as practicable after the proposal for action is sufficiently developed for agency consideration. Scoping may include appropriate pre-application procedures or work conducted prior to publication of the notice of intent (see §§ 1501.3 and 1501.9 of this subchapter).

(b) *Scoping outreach.* When preparing an environmental impact statement, agencies shall facilitate notification to persons and agencies who may be interested or affected by an agency's proposed action, consistent with § 1501.9 of this subchapter. As part of the scoping process, the lead agency may hold a scoping meeting or meetings, publish scoping information, or use other means to communicate with those persons or agencies who may be interested or affected, which the agency may integrate with any other early planning meeting.

(c) *Inviting participation.* As part of the scoping process, and consistent with § 1501.9 of this subchapter, the lead agency shall invite the participation of likely affected Federal, State, Tribal, and local agencies and governments, the proponent of the action, and other likely affected or interested persons (including those who might not be in accord with the action), unless there is a limited exception under § 1507.3(d)(3) of this subchapter.

(d) *Additional scoping responsibilities.* As part of the scoping process, the lead agency shall:

(1) Identify and eliminate from detailed study the issues that are not important or have been covered by prior environmental review(s) (§§ 1501.12 and 1506.3 of this subchapter), narrowing the discussion of these issues in the environmental impact statement to a brief presentation of why they will not be important or providing a reference to their coverage elsewhere.

(2) Allocate assignments for preparation of the environmental impact statement among the lead and cooperating agencies, with the lead agency retaining responsibility for the statement.

(3) Indicate any public environmental assessments and other environmental impact statements that are being or will be prepared and are related to but are not part of the scope of the environmental impact statement under consideration.

(4) Identify other environmental review, authorization, and consultation requirements so the lead and cooperating agencies may prepare other required analyses and studies concurrently and integrated with the environmental impact statement, as provided in § 1502.24 of this subchapter.

(5) Indicate the relationship between the timing of the preparation of environmental analyses and the agencies' tentative planning and decision-making schedule.

(e) *Notice of intent.* As soon as practicable after determining that a proposal is sufficiently developed to allow for meaningful public comment and requires an environmental impact statement, the lead agency shall publish a notice of intent to prepare an environmental impact statement in the **Federal Register**. In addition to the **Federal Register** notice, an agency also may publish notification in accordance with § 1501.9 of this subchapter. The notice shall include, as appropriate:

(1) The purpose and need for the proposed action;

(2) A preliminary description of the proposed action and alternatives the environmental impact statement will consider;

(3) A brief summary of expected effects;

(4) Anticipated permits and other authorizations;

(5) A schedule for the decision-making process;

(6) A description of the public scoping process, including any scoping meeting(s);

(7) A request for comment on alternatives and effects, as well as on relevant information, studies, or analyses with respect to the proposed action;

(8) Contact information for a person within the agency who can answer questions about the proposed action and the environmental impact statement;

(9) Identification of any cooperating and participating agencies, and any information that such agencies require in the notice to facilitate their decisions or authorizations that will rely upon the resulting environmental impact statement; and

(10) A unique identification number for tracking purposes, which the agency shall reference on all environmental documents prepared for the proposed action.

(f) *Notices of withdrawal or cancellation.* If an agency withdraws, cancels, or otherwise ceases the consideration of a proposed action before completing a final environmental impact statement, the agency shall publish a notice in the **Federal Register**.

(g) *Revisions.* An agency shall revise the determinations made under paragraphs (b), (c), and (d) of this section if substantial changes are made later in the proposed action, or if important new circumstances or information arise that bear on the proposal or its effects.

§ 1502.5 Timing.

An agency should commence preparation of an environmental impact statement as close as practicable to the time the agency is developing or receives a proposal so that preparation can be completed in time for the final statement to be included in any recommendation or report on the proposal. The statement shall be prepared early enough so that it can serve as an important practical contribution to the decision-making process and will not be used to rationalize or justify decisions already made (§§ 1501.2 of this subchapter and 1502.2). For instance:

(a) For projects directly undertaken by Federal agencies, the agency shall prepare the environmental impact statement at the feasibility analysis (*e.g.,* go/no-go) stage and may supplement it at a later stage, if necessary.

(b) For applications to the agency requiring an environmental impact statement, the agency shall commence the statement as soon as practicable after receiving the complete application. Federal agencies should work together

and with potential applicants and applicable State, Tribal, and local agencies and governments prior to receipt of the application.

(c) For adjudication, the final environmental impact statement shall normally precede the final staff recommendation and that portion of the public hearing related to the impact study. In appropriate circumstances, the statement may follow preliminary hearings designed to gather information for use in the statement.

(d) For informal rulemaking, the draft environmental impact statement shall normally accompany the proposed rule.

§ 1502.6 Interdisciplinary preparation.

Agencies shall prepare environmental impact statements using an interdisciplinary approach that will ensure the integrated use of the natural and social sciences and the environmental design arts (section 102(2)(A) of NEPA). The disciplines of the preparers shall be appropriate to the scope and issues identified in the scoping process (§ 1502.4 of this subchapter).

§ 1502.7 Page limits.

The text of final environmental impact statements, not including citations or appendices, shall not exceed 150 pages except for proposals of extraordinary complexity, which shall not exceed 300 pages.

§ 1502.8 Writing.

Agencies shall write environmental impact statements in plain language and should use, as relevant, appropriate visual aids or charts so that decision makers and the public can readily understand such statements. Agencies should employ writers of clear prose or editors to write, review, or edit statements, which shall be based upon the analysis and supporting data from the natural and social sciences and the environmental design arts.

§ 1502.9 Draft, final, and supplemental statements.

(a) *Generally.* Except for proposals for legislation as provided in § 1506.8 of this subchapter, agencies shall prepare environmental impact statements in two stages and, where necessary, supplement them as provided in paragraph (d)(1) of this section.

(b) *Draft environmental impact statements.* Agencies shall prepare draft environmental impact statements in accordance with the scope decided upon in the scoping process (§ 1502.4 of this subchapter). The lead agency shall work with the cooperating agencies and shall obtain comments as required in part 1503 of this subchapter. To the fullest extent practicable, the draft statement must meet the requirements established for final statements in section 102(2)(C) of NEPA and in the regulations in this subchapter. If the agency determines that a draft statement is so inadequate as to preclude meaningful analysis, the agency shall prepare and publish a supplemental draft of the appropriate portion. At appropriate points in the draft statement, the agency shall discuss all major points of view on the environmental effects of the alternatives, including the proposed action.

(c) *Final environmental impact statements.* Final environmental impact statements shall consider and respond to comments as required in part 1503 of this subchapter. At appropriate points in the final statement, the agency shall discuss any responsible opposing view that was not adequately discussed in the draft statement and shall indicate the agency's response to the issues raised.

(d) *Supplemental environmental impact statements.* Agencies:

(1) Shall prepare supplements to either draft or final environmental impact statements if a major Federal action remains to occur, and:

(i) The agency makes substantial changes to the proposed action that are relevant to environmental concerns; or

(ii) There are substantial or important new circumstances or information relevant to environmental concerns and bearing on the proposed action or its effects.

(2) May also prepare supplements when the agency determines that the purposes of the Act will be furthered by doing so.

(3) Shall prepare, publish, and file a supplement to a statement (exclusive of scoping (§ 1502.4 of this subchapter)) as a draft and final statement, as is appropriate to the stage of the statement involved, unless the Council approves alternative procedures (§ 1506.12 of this subchapter).

(e) *Reevaluation.* An agency may reevaluate an environmental impact statement and find that changes to the proposed action or new circumstances or information relevant to environmental concerns are not substantial or that the underlying assumptions of the analysis remains valid, and therefore do not require a supplement under paragraph (d) of this section. The agency should document the finding consistent with its agency NEPA procedures (§ 1507.3 of this subchapter), or, if necessary, in a finding of no significant impact supported by an environmental assessment.

§ 1502.10 Recommended format.

(a) Agencies shall use a format for environmental impact statements that will encourage good analysis and clear presentation of the alternatives, including the proposed action. Agencies should use the following standard format for environmental impact statements unless the agency determines that there is a more effective format for communication:

(1) Cover (§ 1501.11);

(2) Summary (§ 1502.12);

(3) Table of contents;

(4) Purpose of and need for action (§ 1502.13);

(5) Alternatives including the proposed action (sections 102(2)(C)(iii) and 102(2)(H) of NEPA) (§ 1502.14);

(6) Affected environment and environmental consequences (especially sections 102(2)(C)(i), (ii), (iv), and (v) of NEPA) (§§ 1502.15 and 1502.16); and

(7) Appendices (§ 1502.19), including the summary of scoping information (§ 1502.17) and the list of preparers (§ 1502.18).

(b) If an agency uses a different format, it shall include paragraph (a) of this section, as further described in §§ 1502.11 through 1502.19, in any appropriate format.

§ 1502.11 Cover.

The environmental impact statement cover shall not exceed one page and shall include:

(a) A list of the lead, joint lead and any cooperating agencies;

(b) The title of the proposed action that is the subject of the statement (and, if appropriate, the titles of related cooperating agency actions), together with the State(s) and county(ies) (or other jurisdiction(s), if applicable) where the action is located;

(c) The name, address, and telephone number of the person at the agency who can supply further information;

(d) A designation of the statement as a draft, final, or draft or final supplement;

(e) A one-paragraph abstract of the statement;

(f) The date by which the agency must receive comments (computed in cooperation with the Environmental Protection Agency under § 1506.10 of this subchapter); and

(g) The identification number included in the notice of intent (§ 1502.4(e)(10)).

§ 1502.12 Summary.

Each environmental impact statement shall contain a summary that adequately and accurately summarizes the statement. The summary shall include the major conclusions and summarize

any disputed issues raised by agencies and the public, any issues to be resolved, and key differences among alternatives, and identify the environmentally preferable alternative or alternatives. Agencies shall write the summary in plain language and should use, as relevant, appropriate visual aids and charts. The summary normally should not exceed 15 pages.

§ 1502.13 Purpose and need.

The environmental impact statement shall include a statement that briefly summarizes the underlying purpose and need for the proposed agency action.

§ 1502.14 Alternatives including the proposed action.

The alternatives section is the heart of the environmental impact statement. The alternatives section should identify the reasonably foreseeable environmental effects of the proposed action and the alternatives in comparative form based on the information and analysis presented in the sections on the affected environment (§ 1502.15) and the environmental consequences (§ 1502.16). In doing so, the analysis should sharply define the issues for the decision maker and the public and provide a clear basis for choice among options. In this section, agencies shall:

(a) Rigorously explore and objectively evaluate reasonable alternatives to the proposed action, and, for alternatives that the agency eliminated from detailed study, briefly discuss the reasons for their elimination. The agency need not consider every conceivable alternative to a proposed action; rather, it shall consider a reasonable range of alternatives that will foster informed decision making. Agencies also may include reasonable alternatives not within the jurisdiction of the lead agency.

(b) Discuss each alternative considered in detail, including the proposed action, so that reviewers may evaluate their comparative merits.

(c) Include the no action alternative.

(d) Identify the agency's preferred alternative or alternatives, if one or more exists, in the draft statement and identify such alternative in the final statement unless another law prohibits the expression of such a preference.

(e) Include appropriate mitigation measures not already included in the proposed action or alternatives.

(f) Identify the environmentally preferable alternative or alternatives. The environmentally preferable alternative will best promote the national environmental policy expressed in section 101 of NEPA by maximizing environmental benefits, such as addressing climate change-related effects or disproportionate and adverse effects on communities with environmental justice concerns; protecting, preserving, or enhancing historic, cultural, Tribal, and natural resources, including rights of Tribal Nations that have been reserved through treaties, statutes, or Executive Orders; or causing the least damage to the biological and physical environment. The environmentally preferable alternative may be the proposed action, the no action alternative, or a reasonable alternative.

§ 1502.15 Affected environment.

(a) The environmental impact statement shall succinctly describe the environment of the area(s) to be affected or created by the alternatives under consideration, including the reasonably foreseeable environmental trends and planned actions in the area(s).

(b) Agencies should use high-quality information, including the best available science and data, to describe reasonably foreseeable environmental trends, including anticipated climate-related changes to the environment, and when such information is lacking, provide relevant information consistent with § 1502.21. This description of baseline environmental conditions and reasonably foreseeable trends should inform the agency's analysis of environmental consequences and mitigation measures (§ 1502.16).

(c) The environmental impact statement may combine the description of the affected environment with evaluation of the environmental consequences (§ 1502.16). The description should be no longer than necessary to understand the relevant affected environment and the effects of the alternatives. Data and analyses in a statement shall be commensurate with the importance of the effect, with less important material summarized, consolidated, or simply referenced. Agencies shall avoid useless bulk in statements and shall concentrate effort and attention on important issues. Verbose descriptions of the affected environment are themselves no measure of the adequacy of an environmental impact statement.

§ 1502.16 Environmental consequences.

(a) The environmental consequences section forms the scientific and analytic basis for the comparisons under § 1502.14. It shall consolidate the discussions of those elements required by sections 102(2)(C)(i), (ii), (iv), and (v) of NEPA that are within the scope of the environmental impact statement and as much of section 102(2)(C)(iii) of NEPA as is necessary to support the comparisons. This section should not duplicate discussions in § 1502.14. The discussion shall include:

(1) The reasonably foreseeable environmental effects of the proposed action and reasonable alternatives to the proposed action and the significance of those effects (§ 1501.3 of this subchapter). The comparison of the proposed action and reasonable alternatives shall be based on the discussion of the effects, focusing on the significant or important effects. The no action alternative should serve as the baseline against which the proposed action and other alternatives are compared.

(2) Any reasonably foreseeable adverse environmental effects that cannot be avoided should the proposal be implemented.

(3) An analysis of the effects of the no action alternative, including any adverse environmental effects.

(4) The relationship between short-term uses of the human environment and the maintenance and enhancement of long-term productivity.

(5) Any irreversible or irretrievable commitments of Federal resources that would be involved in the proposal should it be implemented.

(6) Possible conflicts between the proposed action and the objectives of Federal, regional, State, Tribal, and local plans, policies, and controls for the area concerned, including those addressing climate change (§ 1506.2(d) of this subchapter).

(7) Any reasonably foreseeable climate change-related effects, including the effects of climate change on the proposed action and alternatives.

(8) Energy requirements and conservation potential of various alternatives and mitigation measures.

(9) Natural or depletable resource requirements and conservation potential of various alternatives and mitigation measures.

(10) Any relevant risk reduction, resiliency, or adaptation measures incorporated into the proposed action or alternatives, informed by relevant science and data on the affected environment and expected future conditions.

(11) Urban quality, historic and cultural resources, and the design of the built environment, including the reuse and conservation potential of various alternatives and mitigation measures.

(12) Means to mitigate adverse environmental impacts (if not fully covered under § 1502.14(e)).

(13) Where applicable, economic and technical considerations, including the

economic benefits of the proposed action.

(14) The potential for disproportionate and adverse human health and environmental effects on communities with environmental justice concerns.

(b) Economic or social effects by themselves do not require preparation of an environmental impact statement. However, when the agency determines that economic or social and natural or physical environmental effects are interrelated, the environmental impact statement shall discuss these effects on the human environment.

§ 1502.17 Summary of scoping information.

(a) The draft environmental impact statement shall include a summary of information, including alternatives and analyses, submitted by commenters during the scoping process for consideration by the lead and cooperating agencies in their development of the draft environmental impact statement.

(b) The agency shall append to the draft environmental impact statement or otherwise make publicly available all comments (or summaries thereof where the response has been exceptionally voluminous) received during the scoping process.

§ 1502.18 List of preparers.

The environmental impact statement shall list the names, together with their qualifications (expertise, experience, professional disciplines), of the persons who were primarily responsible for preparing the environmental impact statement or important background papers, including basic components of the statement. Where possible, the environmental impact statement shall identify the persons who are responsible for a particular analysis, including analyses in background papers. Normally the list will not exceed two pages.

§ 1502.19 Appendix.

If an agency prepares an appendix, the agency shall publish it with the environmental impact statement, and it shall consist of, as appropriate:

(a) Material prepared in connection with an environmental impact statement (as distinct from material that is not so prepared and is incorporated by reference (§ 1501.12 of this subchapter)).

(b) Material substantiating any analysis fundamental to the impact statement.

(c) Material relevant to the decision to be made.

(d) For draft environmental impact statements, all comments (or summaries thereof where the response has been exceptionally voluminous) received during the scoping process that identified information for the agency's consideration.

(e) For final environmental impact statements, the comment summaries and responses consistent with § 1503.4 of this chapter.

§ 1502.20 Publication of the environmental impact statement.

Agencies shall publish the entire draft and final environmental impact statements and unchanged statements as provided in § 1503.4(c) of this subchapter. The agency shall transmit the entire statement electronically (or in paper copy, if requested due to economic or other hardship) to:

(a) Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved and any appropriate Federal, State, Tribal, or local agency authorized to develop and enforce environmental standards.

(b) The applicant, if any.

(c) Any person, organization, or agency requesting the entire environmental impact statement.

(d) In the case of a final environmental impact statement, any person, organization, or agency that submitted substantive comments on the draft.

§ 1502.21 Incomplete or unavailable information.

(a) When an agency is evaluating reasonably foreseeable significant adverse effects on the human environment in an environmental impact statement, and there is incomplete or unavailable information, the agency shall make clear that such information is lacking.

(b) If the incomplete information relevant to reasonably foreseeable significant adverse effects is essential to a reasoned choice among alternatives, and the overall costs of obtaining it are not unreasonable, the agency shall include the information in the environmental impact statement.

(c) If the information relevant to reasonably foreseeable significant adverse effects cannot be obtained because the overall costs of obtaining it are unreasonable or the means to obtain it are not known, the agency shall include within the environmental impact statement:

(1) A statement that such information is incomplete or unavailable;

(2) A statement of the relevance of the incomplete or unavailable information to evaluating reasonably foreseeable significant adverse effects on the human environment;

(3) A summary of existing credible scientific evidence that is relevant to evaluating the reasonably foreseeable significant adverse effects on the human environment; and

(4) The agency's evaluation of such effects based upon theoretical approaches or research methods generally accepted in the scientific community.

(d) For the purposes of this section, ''reasonably foreseeable'' includes effects that have catastrophic consequences, even if their probability of occurrence is low, provided that the analysis of the effects is supported by credible scientific evidence, is not based on pure conjecture, and is within the rule of reason.

§ 1502.22 Cost-benefit analysis.

If an agency is considering a cost-benefit analysis for the proposed action relevant to the choice among alternatives with different environmental effects, the agency shall incorporate the cost-benefit analysis by reference or append it to the statement as an aid in evaluating the environmental consequences. In such cases, to assess the adequacy of compliance with section 102(2)(B) of NEPA (ensuring appropriate consideration of unquantified environmental amenities and values in decision making, along with economical and technical considerations), the statement shall discuss the relationship between that analysis and any analyses of unquantified environmental impacts, values, and amenities. For purposes of complying with the Act, agencies need not display the weighing of the merits and drawbacks of the various alternatives in a monetary cost-benefit analysis and should not do so when there are important qualitative considerations. However, an environmental impact statement should at least indicate those considerations, including factors not related to environmental quality, that are likely to be relevant and important to a decision.

§ 1502.23 Methodology and scientific accuracy.

(a) Agencies shall ensure the professional integrity, including scientific integrity, of the discussions and analyses in environmental documents. Agencies shall use high-quality information, such as best available science and reliable data, models, and resources, including existing sources and materials, to analyze effects resulting from a proposed action and alternatives. Agencies may use any reliable data sources, such as remotely gathered

information or statistical models. Agencies should explain any relevant assumptions or limitations of the information or the particular model or methodology selected for use.

(b) Agencies shall identify any methodologies used and shall make explicit reference to the scientific and other sources relied upon for conclusions in the statement. Agencies may place discussion of methodology in an appendix. Nothing in this section is intended to prohibit agencies from compliance with the requirements of other statutes pertaining to scientific and technical research.

(c) Where appropriate, agencies shall use projections when evaluating the reasonably foreseeable effects, including climate change-related effects. Such projections may employ mathematical or other models that project a range of possible future outcomes, so long as agencies disclose the relevant assumptions or limitations.

§ 1502.24 Environmental review and consultation requirements.

(a) To the fullest extent possible, agencies shall prepare draft environmental impact statements concurrent and integrated with environmental impact analyses and related surveys and studies required by all other Federal environmental review laws and Executive orders applicable to the proposed action, including the Fish and Wildlife Coordination Act (16 U.S.C. 661 *et seq.*), the National Historic Preservation Act of 1966 (54 U.S.C. 300101 *et seq.*), and the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

(b) The draft environmental impact statement shall list all Federal permits, licenses, and other authorizations that must be obtained in implementing the proposal. If it is uncertain whether a Federal permit, license, or other authorization is necessary, the draft environmental impact statement shall so indicate.

PART 1503—COMMENTING ON ENVIRONMENTAL IMPACT STATEMENTS

§ 1503.1 Inviting comments and requesting information and analyses.

(a) After preparing a draft environmental impact statement and before preparing a final environmental impact statement the agency shall:

(1) Obtain the comments of any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved or is authorized to develop and enforce environmental standards; and

(2) Request the comments of:

(i) Appropriate State, Tribal, and local agencies that are authorized to develop and enforce environmental standards;

(ii) State, Tribal, or local governments that may be affected by the proposed action;

(iii) Any agency that has requested it receive statements on actions of the kind proposed;

(iv) The applicant, if any; and

(v) The public, affirmatively soliciting comments in a manner designed to inform those persons or organizations who may be interested in or affected by the proposed action.

(b) An agency may request comments on a final environmental impact statement before the final decision and set a deadline for providing such comments. Other agencies or persons may make comments consistent with the time periods under § 1506.10 of this subchapter.

(c) An agency shall provide for electronic submission of public comments, with reasonable measures to ensure the comment process is accessible to affected persons.

§ 1503.2 Duty to comment.

Cooperating agencies and agencies that are authorized to develop and enforce environmental standards shall comment on environmental impact statements within their jurisdiction, expertise, or authority within the time period specified for comment in § 1506.10 of this subchapter. A Federal agency may reply that it has no comment. If a cooperating agency is satisfied that the environmental impact statement adequately reflects its views, it should reply that it has no comment.

§ 1503.3 Specificity of comments and information.

(a) To promote informed decision making, comments on an environmental impact statement or on a proposed action shall be as specific as possible, and may address either the adequacy of the statement or the merits of the alternatives discussed or both. Comments should explain why the issues raised are important to the consideration of potential environmental effects and alternatives to the proposed action. Where possible, comments should reference the corresponding section or page number of the draft environmental impact statement, propose specific changes to those parts of the statement, and describe any data, sources, or methodologies that support the proposed changes.

(b) When a participating agency criticizes a lead agency's predictive methodology, the participating agency should describe the alternative methodology that it prefers and why.

(c) A cooperating agency shall specify in its comments whether it needs additional information to fulfill other applicable environmental review or consultation requirements and what information it needs. In particular, it shall specify any additional information it needs to comment adequately on the draft statement's analysis of significant effects associated with the granting or approving by that cooperating agency of necessary Federal permits, licenses, or authorizations.

(d) A cooperating agency with jurisdiction by law shall specify mitigation measures it considers necessary to allow the agency to grant or approve applicable authorizations or concurrences.

§ 1503.4 Response to comments.

(a) An agency preparing a final environmental impact statement shall consider substantive comments timely submitted during the public comment period. The agency shall respond to individual comments or groups of comments. In the final environmental impact statement, the agency may respond by:

(1) Modifying alternatives including the proposed action;

(2) Developing and evaluating alternatives not previously given serious consideration by the agency;

(3) Supplementing, improving, or modifying its analyses;

(4) Making factual corrections; or

(5) Explaining why the comments do not warrant further agency response, recognizing that agencies are not required to respond to each comment.

(b) An agency shall append or otherwise publish all substantive comments received on the draft statement (or summaries thereof where the response has been exceptionally voluminous).

(c) If changes in response to comments are minor and are confined to the responses described in paragraphs (a)(4) and (5) of this section, an agency may write any changes on errata sheets and attach the responses to the statement instead of rewriting the draft statement. In such cases, the agency shall publish the final statement (§ 1502.20 of this subchapter), which includes the draft statement, the comments, responses to those comments, and errata sheets. The agency shall file the final statement with the Environmental Protection Agency (§ 1506.10 of this subchapter).

PART 1504—PRE–DECISIONAL REFERRALS TO THE COUNCIL OF PROPOSED FEDERAL ACTIONS DETERMINED TO BE ENVIRONMENTALLY UNSATISFACTORY

§ 1504.1 Purpose.

(a) This part establishes procedures for referring to the Council Federal interagency disagreements concerning proposed major Federal actions that might cause unsatisfactory environmental effects. It provides means for early resolution of such disagreements, and encourages Federal agencies to engage with each other as early as practicable to resolve interagency disagreements concerning proposed major Federal actions before referring disputes to the Council. This part also establishes procedures for Federal agencies to submit a request to the Council to provide informal dispute resolution on NEPA issues before formally referring disputes to the Council.

(b) Section 309 of the Clean Air Act (42 U.S.C. 7609) directs the Administrator of the Environmental Protection Agency to review and comment publicly on the environmental impacts of Federal activities, including actions for which agencies prepare environmental impact statements. If, after this review, the Administrator determines that the matter is ''unsatisfactory from the standpoint of public health or welfare or environmental quality,'' section 309 directs that the matter be referred to the Council.

(c) Under section 102(2)(C) of NEPA (42 U.S.C. 4332(2)(C)), other Federal agencies may prepare similar reviews of environmental impact statements, including judgments on the acceptability of anticipated environmental impacts. These agencies must make these reviews available to the President, the Council, and the public.

§ 1504.2 Early dispute resolution.

(a) Federal agencies should engage in interagency coordination and collaboration in their planning and decision-making processes and should identify and resolve disputes concerning proposed major Federal actions early in the NEPA process. To the extent practicable, agencies should elevate issues to appropriate agency officials or the Council in a timely manner that will accommodate schedules consistent with § 1501.10 of this subchapter.

(b) A Federal agency may request that the Council engage in informal dispute resolution to provide recommendations on how to resolve an interagency dispute concerning an environmental review. In making the request, the agency shall provide the Council with a summary of the proposed action, information on the disputed issues, and agency points of contact.

(c) In response to a request for informal dispute resolution, the Council may request additional information, provide non-binding recommendations, convene meetings of those agency decision makers necessary to resolve disputes, or determine that informal dispute resolution is unhelpful or inappropriate.

§ 1504.3 Criteria and procedure for referrals and response.

(a) Federal agencies should make environmental referrals to the Council only after concerted, timely (as early as practicable in the process), but unsuccessful attempts to resolve differences with the lead agency. In determining what environmental objections to the matter are appropriate to refer to the Council, an agency should weigh potential adverse environmental effects, considering:

(1) Possible violation of national environmental standards or policies;

(2) Severity;

(3) Geographical scope;

(4) Duration;

(5) Importance as precedents;

(6) Availability of environmentally preferable alternatives; and

(7) Economic and technical considerations, including the economic costs of delaying or impeding the decision making of the agencies involved in the action.

(b) A Federal agency making the referral to the Council shall:

(1) Notify the lead agency at the earliest possible time that it intends to refer a matter to the Council unless a satisfactory agreement is reached;

(2) Include such a notification whenever practicable in the referring agency's comments on the environmental assessment or draft environmental impact statement;

(3) Identify any essential information that is lacking and request that the lead agency make it available at the earliest possible time; and

(4) Send copies of the referring agency's views to the Council.

(c) The referring agency shall deliver its referral to the Council no later than 25 days after the lead agency has made the final environmental impact statement available to the Environmental Protection Agency, participating agencies, and the public, and in the case of an environmental assessment, no later than 25 days after the lead agency makes it available. Except when the lead agency grants an extension of this period, the Council will not accept a referral after that date.

(d) The referral shall consist of:

(1) A copy of the letter signed by the head of the referring agency and delivered to the lead agency informing the lead agency of the referral and the reasons for it; and

(2) A statement supported by factual evidence leading to the conclusion that the matter is unsatisfactory from the standpoint of public health or welfare or environmental quality. The statement shall:

(i) Identify any disputed material facts and incorporate (by reference if appropriate) agreed upon facts;

(ii) Identify any existing environmental requirements or policies that would be violated by the matter;

(iii) Present the reasons for the referral;

(iv) Contain a finding by the agency whether the issue raised is of national importance because of the threat to national environmental resources or policies or for some other reason;

(v) Review the steps taken by the referring agency to bring its concerns to the attention of the lead agency at the earliest possible time; and

(vi) Give the referring agency's recommendations as to what mitigation alternative, further study, or other course of action (including abandonment of the matter) are necessary to remedy the situation.

(e) No later than 25 days after the referral to the Council, the lead agency may deliver a response to the Council and the referring agency. If the lead agency requests more time and gives assurance that the matter will not go forward in the interim, the Council may grant an extension. The response shall:

(1) Address fully the issues raised in the referral;

(2) Be supported by evidence and explanations, as appropriate; and

(3) Give the lead agency's response to the referring agency's recommendations.

(f) Applicants may provide views in writing to the Council no later than the response.

(g) No later than 25 days after receipt of both the referral and any response or upon being informed that there will be no response (unless the lead agency agrees to a longer time), the Council may take one or more of the following actions:

(1) Conclude that the process of referral and response has successfully resolved the problem.

(2) Initiate discussions with the agencies with the objective of mediation with referring and lead agencies.

(3) Obtain additional views and information.

(4) Determine that the issue is not one of national importance and request the referring and lead agencies to pursue their decision process.

(5) Determine that the referring and lead agencies should further negotiate the issue, and the issue is not appropriate for Council consideration until one or more heads of agencies report to the Council that the agencies' disagreements are irreconcilable.

(6) Publish its findings and recommendations (including, where appropriate, a finding that the submitted evidence does not support the position of an agency).

(7) When appropriate, submit the referral and the response together with the Council's recommendation to the President for action.

(h) The Council shall take no longer than 60 days to complete the actions specified in paragraph (g)(2), (3), or (5) of this section.

(i) The referral process is not intended to create any private rights of action or to be judicially reviewable because any voluntary resolutions by the agency parties do not represent final agency action and instead are only provisional and dependent on later consistent action by the action agencies.

PART 1505—NEPA AND AGENCY DECISION MAKING

§ 1505.1 [Reserved]

§ 1505.2 Record of decision in cases requiring environmental impact statements.

At the time of its decision (§ 1506.10 of this subchapter) or, if appropriate, its recommendation to Congress, each agency shall prepare and timely publish a concise public record of decision or joint record of decision. The record, which each agency may integrate into any other record it prepares, shall:

(a) State the decision.

(b) Identify alternatives considered by the agency in reaching its decision. The agency also shall specify the environmentally preferable alternative or alternatives (§ 1502.14(f) of this subchapter). The agency may discuss preferences among alternatives based on relevant factors, including environmental, economic, and technical considerations and agency statutory missions. The agency shall identify and discuss all such factors, including any essential considerations of national policy, that the agency balanced in making its decision and state how those considerations entered into its decision.

(c) State whether the agency has adopted all practicable means to mitigate environmental harm from the alternative selected, and if not, why the agency did not. When an agency includes mitigation as a component of the proposed action and relies on implementation of that mitigation to analyze the reasonably foreseeable environmental effects, the mitigation shall be enforceable, such as through permit conditions, agreements, or other measures. The agency shall identify the authority for enforceable mitigation, and adopt a monitoring and compliance plan consistent with § 1505.3(c).

§ 1505.3 Implementing the decision.

(a) Agencies may provide for monitoring to assure that their decisions are carried out and should do so in important cases. Mitigation (§ 1505.2(c)) and other conditions established in the environmental impact statement or during its review and committed as part of the decision shall be implemented by the lead agency or other appropriate consenting agency. The lead agency shall:

(1) Include appropriate conditions in grants, permits, or other approvals; and

(2) Condition funding of actions on mitigation.

(b) The lead or cooperating agency should, where relevant and appropriate, incorporate mitigation measures that address or ameliorate significant adverse human health and environmental effects of proposed Federal actions that disproportionately and adversely affect communities with environmental justice concerns.

(c) The lead or cooperating agency shall prepare a monitoring and compliance plan when the environmental assessment or environmental impact statement relies on mitigation as a component of the proposed action to analyze the reasonably foreseeable environmental effects, including to determine the significance of those effects, and the agency incorporates the mitigation into a record of decision, finding of no significant impact, or separate document, consistent with the following:

(1) *Contents.* The agency should tailor the plan to the complexity of the mitigation committed to and include:

(i) A basic description of the mitigation measure or measures;

(ii) The parties responsible for monitoring and implementing the mitigation;

(iii) If appropriate, how monitoring information will be made publicly available;

(iv) The anticipated timeframe for implementing and completing mitigation;

(v) The standards for determining compliance with the mitigation and the consequences of non-compliance; and

(vi) How the mitigation will be funded.

(2) *No ongoing Federal action.* An agency does not need to supplement its environmental impact statement or environmental assessment or revise its record of decision or finding of no significant impact or separate decision document based solely on new information developed through the monitoring and compliance plan.

PART 1506—OTHER REQUIREMENTS OF NEPA

§ 1506.1 Limitations on actions during NEPA process.

(a) Except as provided in paragraphs (b) and (c) of this section, until an agency issues a finding of no significant impact, as provided in § 1501.6 of this subchapter, or record of decision, as provided in § 1505.2 of this subchapter, no action concerning the proposal may be taken that would:

(1) Have an adverse environmental effect; or

(2) Limit the choice of reasonable alternatives.

(b) If an agency is considering an application from a non-Federal entity and is aware that the applicant is about to take an action within the agency's jurisdiction that would meet either of the criteria in paragraph (a) of this section, then the agency shall promptly notify the applicant that the agency will take appropriate action to ensure that the objectives and procedures of NEPA are achieved. This section does not preclude development by applicants of plans or designs or performance of other activities necessary to support an application for Federal, State, Tribal, or local permits or assistance. An agency considering a proposed action for Federal funding may authorize such activities, including, but not limited to, acquisition of interests in land (*e.g.,* fee simple, rights-of-way, and conservation easements), purchase of long lead-time equipment, and purchase options made by applicants, if the agency determines that such activities would not limit the choice of reasonable alternatives and notifies the applicant that the agency retains discretion to select any reasonable alternative or the no action alternative regardless of any potential prior activity taken by the applicant prior to the conclusion of the NEPA process.

(c) While work on a programmatic environmental review is in progress and the action is not covered by an existing programmatic review, agencies shall not

undertake in the interim any major Federal action covered by the program that may significantly affect the quality of the human environment unless such action:

(1) Is justified independently of the program;

(2) Is itself accompanied by an adequate environmental review; and

(3) Will not prejudice the ultimate decision on the program. Interim action prejudices the ultimate decision on the program when it tends to determine subsequent development or limit alternatives.

§ 1506.2 Elimination of duplication with State, Tribal, and local procedures.

(a) Federal agencies are authorized to cooperate with State, Tribal, and local agencies that are responsible for preparing environmental documents, including those prepared pursuant to section 102(2)(G) of NEPA.

(b) To the fullest extent practicable unless specifically prohibited by law, agencies shall cooperate with State, Tribal, and local agencies to reduce duplication between NEPA and State, Tribal, and local requirements, including through use of studies, analysis, and decisions developed by State, Tribal, or local agencies. Except for cases covered by paragraph (a) of this section, such cooperation shall include, to the fullest extent practicable:

(1) Joint planning processes.

(2) Joint environmental research and studies.

(3) Joint public hearings (except where otherwise provided by statute).

(4) Joint environmental assessments.

(c) To the fullest extent practicable unless specifically prohibited by law, agencies shall cooperate with State, Tribal, and local agencies to reduce duplication between NEPA and comparable State, Tribal, and local requirements. Such cooperation shall include, to the fullest extent practicable, joint environmental impact statements. In such cases, one or more Federal agencies and one or more State, Tribal, or local agencies shall be joint lead agencies. Where State or Tribal laws or local ordinances have environmental impact statement or similar requirements in addition to but not in conflict with those in NEPA, Federal agencies may cooperate in fulfilling these requirements, as well as those of Federal laws, so that one document will comply with all applicable laws.

(d) To better integrate environmental impact statements into State, Tribal, or local planning processes, environmental impact statements shall discuss any inconsistency of a proposed action with any approved State, Tribal, or local plan or law (whether or not federally sanctioned). Where an inconsistency exists, the statement should describe the extent to which the agency would reconcile its proposed action with the plan or law. While the statement should discuss any inconsistencies, NEPA does not require reconciliation.

§ 1506.3 Adoption.

(a) *Generally.* An agency may adopt a draft or final environmental impact statement, environmental assessment, or portion thereof, or categorical exclusion determination, consistent with this section.

(b) *Environmental impact statements.* An agency may adopt a draft or final environmental impact statement, or portion thereof, provided that the adopting agency conducts an independent review of the statement and concludes that it meets the standards for an adequate statement, pursuant to the regulations in this subchapter and the adopting agency's NEPA procedures.

(1) If the actions covered by the original environmental impact statement and the proposed action are substantially the same, the adopting agency shall republish and file it as a final statement consistent with § 1506.9 of this subchapter. If the actions are not substantially the same or the adopting agency determines that the statement requires supplementation, the adopting agency shall treat the statement as a draft, supplement or reevaluate it as necessary, and republish and file it, consistent with § 1506.9 of this subchapter.

(2) Notwithstanding paragraph (b)(1) of this section, if a cooperating agency does not issue a record of decision jointly or concurrently consistent with § 1505.2 of this subchapter, a cooperating agency may issue a record of decision adopting the environmental impact statement of a lead agency without republication.

(c) *Environmental assessments.* An agency may adopt an environmental assessment, or portion thereof, if the actions covered by the original environmental assessment and the proposed action are substantially the same, and the assessment meets the standards for an adequate environmental assessment under the regulations in this subchapter and the adopting agency's NEPA procedures. If the actions are not substantially the same or the adopting agency determines that the environmental assessment requires supplementation, the adopting agency may adopt the environmental assessment, and supplement or reevaluate it as necessary, in its finding of no significant impact and provide notice consistent with § 1501.6 of this subchapter.

(d) *Categorical exclusion determinations.* An agency may adopt another agency's determination that a categorical exclusion applies to a particular proposed action if the action covered by that determination and the adopting agency's proposed action are substantially the same.

(1) The adopting agency shall document its adoption, including the determination that its proposed action is substantially the same as the action covered by the original categorical exclusion determination and that there are no extraordinary circumstances present that require the preparation of an environmental assessment or environmental impact statement.

(2) The adopting agency shall publish its adoption determination on an agency website or otherwise make it publicly available.

(e) *Identification of certain circumstances.* The adopting agency shall specify if one of the following circumstances is present:

(1) The agency is adopting an environmental assessment or environmental impact statement that is not final within the agency that prepared it.

(2) The action assessed in the environmental assessment or environmental impact statement is the subject of a referral under part 1504 of this subchapter.

(3) The environmental assessment or environmental impact statement's adequacy is the subject of a judicial action that is not final.

§ 1506.4 Combining documents.

Agencies should combine, to the fullest extent practicable, any environmental document with any other agency document to reduce duplication and paperwork.

§ 1506.5 Agency responsibility for environmental documents.

(a) The agency is responsible for the accuracy, scope (§ 1501.3(b) of this subchapter), and content of environmental documents and shall ensure they are prepared with professional and scientific integrity, using reliable data and resources, regardless of whether they are prepared by the agency or a contractor under the supervision of the agency or by the applicant or project sponsor under procedures the agency adopts pursuant to section 107(f) of NEPA and § 1507.3(c)(1) of this subchapter. The agency shall exercise its independent judgment and briefly document its

determination that an environmental document meets the standards under NEPA, the regulations in this subchapter, and the agency's NEPA procedures.

(b) An agency may require an applicant to submit environmental information for possible use by the agency in preparing an environmental document. An agency also may authorize a contractor to prepare an environmental assessment or environmental impact statement under the supervision of the agency and may authorize a contractor to draft a finding of no significant impact or record of decision, but the agency is responsible for its accuracy, scope, and contents.

(1) The agency should assist the applicant by outlining the types of information required for the preparation of environmental documents. The agency shall provide guidance to the contractor and participate in and supervise the document's preparation.

(2) The agency shall independently evaluate the information submitted and the environmental document and shall be responsible for their accuracy, scope, and contents, and document its evaluation in the environmental document.

(3) The agency shall include in the environmental document the names and qualifications of the persons preparing environmental documents, and conducting the independent evaluation of any information submitted or environmental documents prepared by a contractor, such as in the list of preparers for environmental impact statements (§ 1502.18 of this subchapter). It is the intent of this paragraph (b)(3) that acceptable work not be redone, but that it be verified by the agency.

(4) The lead agency or cooperating agency, where appropriate, shall prepare a disclosure statement for the contractor's execution specifying that the contractor has no financial or other interest in the outcome of the action. Such statement need not include privileged or confidential trade secrets or other confidential business information.

(5) Nothing in this section is intended to prohibit an agency from requesting any person, including the applicant, to submit information to it or to prohibit any person from submitting information to an agency for use in preparing environmental documents.

§ 1506.6 [Reserved]

§ 1506.7 Further guidance.

(a) The Council may provide further guidance concerning NEPA and its procedures.

(b) To the extent that Council guidance issued prior to [EFFECTIVE DATE OF THE FINAL RULE] is in conflict with this subchapter, the provisions of this subchapter apply.

§ 1506.8 Proposals for legislation.

(a) When developing legislation, agencies shall integrate the NEPA process for proposals for legislation significantly affecting the quality of the human environment with the legislative process of the Congress. Technical drafting assistance does not by itself constitute a legislative proposal. Only the agency that has primary responsibility for the subject matter involved will prepare a legislative environmental impact statement.

(b) A legislative environmental impact statement is the detailed statement required by law to be included in an agency's recommendation or report on a legislative proposal to Congress. A legislative environmental impact statement shall be considered part of the formal transmittal of a legislative proposal to Congress; however, it may be transmitted to Congress up to 30 days later to allow time for completion of an accurate statement that can serve as the basis for public and Congressional debate. The statement must be available in time for Congressional hearings and deliberations.

(c) Preparation of a legislative environmental impact statement shall conform to the requirements of the regulations in this subchapter, except as follows:

(1) There need not be a scoping process.

(2) Agencies shall prepare the legislative statement in the same manner as a draft environmental impact statement and need not prepare a final statement unless any of the following conditions exist. In such cases, the agency shall prepare and publish the statements consistent with §§ 1503.1 of this subchapter and 1506.11:

(i) A Congressional committee with jurisdiction over the proposal has a rule requiring both draft and final environmental impact statements.

(ii) The proposal results from a study process required by statute (such as those required by the Wild and Scenic Rivers Act (16 U.S.C. 1271 *et seq.*)).

(iii) Legislative approval is sought for Federal or federally assisted construction or other projects that the agency recommends be located at specific geographic locations. For proposals requiring an environmental impact statement for the acquisition of space by the General Services Administration, a draft statement shall accompany the Prospectus or the 11(b) Report of Building Project Surveys to the Congress, and a final statement shall be completed before site acquisition.

(iv) The agency decides to prepare draft and final statements.

(d) Comments on the legislative statement shall be given to the lead agency, which shall forward them along with its own responses to the Congressional committees with jurisdiction.

§ 1506.9 Filing requirements.

(a) Agencies shall file environmental impact statements together with comments and responses with the Environmental Protection Agency, Office of Federal Activities, consistent with the Environmental Protection Agency's procedures.

(b) Agencies shall file statements with the Environmental Protection Agency no earlier than they are also transmitted to participating agencies and made available to the public. The Environmental Protection Agency may issue guidelines to agencies to implement its responsibilities under this section and § 1506.10.

(c) Agencies shall notify the Environmental Protection Agency when they adopt an environmental impact statement consistent with § 1506.3(b).

§ 1506.10 Timing of agency action.

(a) The Environmental Protection Agency shall publish a notice in the **Federal Register** each week of the environmental impact statements filed since its prior notice. The minimum time periods set forth in this section are calculated from the date of publication of this notice.

(b) Unless otherwise provided by law, including statutory provisions for combining a final environmental impact statement and record of decision, Federal agencies shall not make or issue a record of decision under § 1505.2 of this subchapter for the proposed action until the later of the following dates:

(1) 90 days after publication of the notice described in paragraph (a) of this section for a draft environmental impact statement.

(2) 30 days after publication of the notice described in paragraph (a) of this section for a final environmental impact statement.

(c) An agency may make an exception to the rule on timing set forth in paragraph (b) of this section for a

proposed action in the following circumstances:

(1) Some agencies have formally established administrative review processes (*e.g.,* appeals, objections, protests), which may be initiated prior to or after filing and publication of the final environmental impact statement with the Environmental Protection Agency, that allow other agencies or the public to raise issues about a decision and make their views known. In such cases where a real opportunity exists to alter the decision, the agency may make and record the decision at the same time it publishes the environmental impact statement. This means that the period for administrative review of the decision and the 30-day period set forth in paragraph (b)(2) of this section may run concurrently. In such cases, the environmental impact statement shall explain the timing and the public's right of administrative review and provide notification consistent with § 1506.9; or

(2) An agency engaged in rulemaking under the Administrative Procedure Act or other statute for the purpose of protecting the public health or safety may waive the time period in paragraph (b)(2) of this section, publish a decision on the final rule simultaneously with publication of the notice of the availability of the final environmental impact statement, and provide notification consistent with § 1506.10, as described in paragraph (a) of this section.

(d) If an agency files the final environmental impact statement within 90 days of the filing of the draft environmental impact statement with the Environmental Protection Agency, the minimum 30-day and 90-day periods may run concurrently. However, subject to paragraph (e) of this section, agencies shall allow at least 45 days for comments on draft statements.

(e) The lead agency may extend the minimum periods in paragraph (b) of this section and provide notification consistent with § 1506.10. Upon a showing by the lead agency of compelling reasons of national policy, the Environmental Protection Agency may reduce the minimum periods and, upon a showing by any other Federal agency of compelling reasons of national policy, also may extend the minimum periods, but only after consultation with the lead agency. The lead agency may modify the minimum periods when necessary to comply with other specific statutory requirements (§ 1507.3(d)(4) of this subchapter). Failure to file timely comments shall not be a sufficient reason for extending a period. If the lead agency does not concur with the extension of time, the Environmental Protection Agency may not extend it for more than 30 days. When the Environmental Protection Agency reduces or extends any period it shall notify the Council.

§ 1506.11 Emergencies.

Where emergency circumstances make it necessary to take an action with significant effects without observing the provisions of the regulations in this subchapter, the Federal agency taking the action should consult with the Council about alternative arrangements for compliance with section 102(2)(C) of NEPA. Agencies and the Council will limit such arrangements to actions necessary to control the immediate impacts of the emergency. Alternative arrangements do not waive the requirement to comply with the statute, but establish an alternative means for NEPA compliance.

§ 1506.12 Innovative approaches to NEPA reviews.

(a) The Council may authorize an innovative approach to NEPA compliance that allows an agency to comply with the Act following procedures modified from the requirements of the regulations in this subchapter, to facilitate sound and efficient environmental review for actions to address extreme environmental challenges consistent with section 101 of NEPA. Examples of extreme environmental challenges may relate to sea level rise, increased wildfire risk, or bolstering the resilience of infrastructure to increased disaster risk due to climate change; water scarcity; degraded water or air quality; disproportionate and adverse effects on communities with environmental justice concerns; imminent or reasonably foreseeable loss of historic, cultural, or Tribal resources; species loss; and impaired ecosystem health.

(b) The Council may approve an innovative approach if it is consistent with this section, and such approval does not waive the requirement to comply with the statute, but establishes an alternative means for NEPA compliance.

(c) An agency request for an innovative approach shall:

(1) Identify each provision of this subchapter from which the agency seeks a modification and how the innovative approach the agency proposes to ensure compliance with NEPA;

(2) Explain the extreme environmental challenge the approach would address, why the alternative means are needed to address the challenge, and how the alternative means would facilitate the sound and efficient environmental review; and

(3) Consult with any potential cooperating agencies and include a summary of their comments.

(d) The Council shall evaluate the agency's request within 60 days to determine if it meets the requirements in this section. The Council may:

(1) Approve the request for modification;

(2) Approve the request for modification with revisions; or

(3) Deny the request for modification.

(e) The Council shall publish on its website any request for modification that it has approved, approved with revisions, or denied.

§ 1506.13 Effective date.

The regulations in this subchapter apply to any NEPA process begun after [EFFECTIVE DATE OF THE FINAL RULE]. An agency may apply the regulations in this subchapter to ongoing activities and environmental documents begun before [EFFECTIVE DATE OF THE FINAL RULE].

PART 1507—AGENCY COMPLIANCE

§ 1507.1 Compliance.

All agencies of the Federal Government shall comply with the regulations in this subchapter. It is the intent of these regulations to allow each agency flexibility in adapting its implementing procedures authorized by § 1507.3 to the requirements of other applicable laws.

§ 1507.2 Agency capability to comply.

Each agency shall be capable (in terms of personnel and other resources) of complying with the requirements of NEPA and the regulations in this subchapter. Such compliance may include use of the resources of other agencies, applicants, and other participants in the NEPA process, but the agency using the resources shall itself have sufficient capability to evaluate what others do for it and account for the contributions of others. Agencies shall:

(a) Agencies shall designate a senior agency official to be responsible for overall review of agency NEPA compliance, including resolving implementation issues, and a Chief Public Engagement Officer to be responsible for facilitating community engagement across the agency and, where appropriate, the provision of technical assistance to communities.

(b) Fulfill the requirements of section 102(2)(A) of NEPA to utilize a systematic, interdisciplinary approach that will ensure the integrated use of the

natural and social sciences and the environmental design arts in planning and in decision making that may have an impact on the human environment.

(c) Identify methods and procedures required by section 102(2)(B) of NEPA to ensure that presently unquantified environmental amenities and values may be given appropriate consideration.

(d) Prepare adequate environmental impact statements pursuant to section 102(2)(C) of NEPA and cooperate on the development of statements in the areas where the agency has jurisdiction by law or special expertise or is authorized to develop and enforce environmental standards.

(e) Ensure environmental documents are prepared with professional integrity, including scientific integrity, consistent with section 102(2)(D) of NEPA.

(f) Make use of reliable data and resources in carrying out their responsibilities under NEPA, consistent with section 102(2)(E) of NEPA.

(g) Study, develop, and describe technically and economically feasible alternatives, consistent with section 102(2)(F) of NEPA.

(h) Study, develop, and describe alternatives to recommended courses of action in any proposal that involves unresolved conflicts concerning alternative uses of available resources, consistent with section 102(2)(H) of NEPA.

(i) Comply with the requirement of section 102(2)(K) of NEPA that the agency initiate and utilize ecological information in the planning and development of resource-oriented projects.

(j) Fulfill the requirements of sections 102(2)(I), 102(2)(J), and 102(2)(L), of NEPA, and Executive Order 11514, Protection and Enhancement of Environmental Quality, section 2, as amended by Executive Order 11991, Relating to Protection and Enhancement of Environmental Quality.

§ 1507.3 Agency NEPA procedures.

(a) The Council has determined that the categorical exclusions contained in agency NEPA procedures as of [EFFECTIVE DATE OF THE FINAL RULE] are consistent with this subchapter.

(b) No more than 12 months after [EFFECTIVE DATE OF THE FINAL RULE], or 9 months after the establishment of an agency, whichever comes later, each agency shall develop or revise, as necessary, proposed procedures to implement the regulations in this subchapter, facilitate efficient decision making, and ensure that agencies make decisions in accordance with the policies and requirements of the Act. When the agency is a department, it may be efficient for major subunits (with the consent of the department) to adopt their own procedures.

(1) Each agency shall consult with the Council while developing or revising its proposed procedures and before publishing them in the **Federal Register** for comment. Agencies with similar programs should consult with each other and the Council to coordinate their procedures, especially for programs requesting similar information from applicants.

(2) Agencies shall provide an opportunity for public review and review by the Council for conformity with the Act and the regulations in this subchapter before issuing their final procedures. The Council shall complete its review within 30 days of the receipt of the proposed final procedures. Once in effect, agencies shall publish their NEPA procedures and ensure that they are readily available to the public. Agencies shall continue to review their policies and procedures, in consultation with the Council, to revise them as necessary to ensure full compliance with the purposes and provisions of the Act.

(3) The issuance or update of agency procedures is not subject to NEPA review under this subchapter.

(c) Agency procedures shall:

(1) Designate the major decision points for the agency's programs and actions subject to NEPA, ensuring that the NEPA process begins at the earliest reasonable time, consistent with § 1501.2 of this subchapter, and aligns with the corresponding decision points;

(2) Require that relevant environmental documents, comments, and responses be part of the record in rulemaking and adjudicatory proceedings;

(3) Integrate the environmental review into the decision-making process by requiring that relevant environmental documents, comments, and responses accompany the proposal through existing agency review processes so that decision makers use them in making decisions;

(4) Require that the alternatives considered by the decision maker are encompassed by the range of alternatives discussed in the relevant environmental documents and that the decision maker consider the alternatives described in the environmental documents. If another decision document accompanies the relevant environmental documents to the decision maker, agencies are encouraged to make available to the public before the decision is made any part of that document that relates to the comparison of alternatives;

(5) Require the combination of environmental documents with other agency documents to facilitate sound and efficient decision making and avoid duplication, where consistent with applicable statutory requirements;

(6) Include those procedures required by §§ 1501.2(b)(4) (assistance to applicants);

(7) Include specific criteria for and identification of those typical classes of action that normally:

(i) Require environmental impact statements; and

(ii) Require environmental assessments but not necessarily environmental impact statements;

(8) Establish categorical exclusions and identify extraordinary circumstances. When establishing new or revising existing categorical exclusions, agencies shall:

(i) Identify when documentation of a determination that a categorical exclusion applies to a proposed action is required;

(ii) Substantiate the proposed new or revised categorical exclusion with sufficient information to conclude that the category of actions does not have a significant effect, individually or in the aggregate, on the human environment and provide this substantiation in a written record that is made publicly available as part of the notice and comment process (§ 1507.3(b)(1) and (2)); and

(iii) Describe how the agency will consider extraordinary circumstances in determining whether additional analysis in an environmental assessment or environmental impact statement is required;

(9) Include a process for reviewing the agency's categorical exclusions at least every 10 years;

(10) Include a process for introducing a supplement to an environmental assessment or environmental impact statement into its formal administrative record, if such a record exists;

(11) Explain where interested persons can get information or status reports on environmental impact statements, environmental assessments, and other elements of the NEPA process; and

(12) Where applicable, include procedures to allow a project sponsor to prepare environmental assessments and environmental impact statements under the agency's supervision consistent with § 1506.5 of this subchapter.

(d) Agency procedures also may:

(1) Identify activities or decisions that are not subject to NEPA;

(2) Include processes for consideration of emergency actions that would not result in significant effects;

(3) Include specific criteria for providing limited exceptions to the provisions of the regulations in this subchapter for classified proposals. These are proposed actions that are specifically authorized under criteria established by an Executive order or statute to be kept secret in the interest of national defense or foreign policy and are in fact properly classified pursuant to such Executive order or statute. Agencies may safeguard and restrict from public dissemination environmental assessments and environmental impact statements that address classified proposals in accordance with agencies' own regulations applicable to classified information. Agencies should organize these documents so that classified portions are included as annexes, so that the agencies can make the unclassified portions available to the public; and

(4) Provide for periods of time other than those presented in § 1506.10 of this subchapter when necessary to comply with other specific statutory requirements, including requirements of lead or cooperating agencies.

§ 1507.4 Agency NEPA program information.

(a) To allow agencies and the public to efficiently and effectively access information about NEPA reviews, agencies shall provide for agency websites or other information technology tools to make available documents, relevant notices, and other relevant information for use by agencies, applicants, and interested persons. The website or other such means of publication shall include the agency's NEPA procedures, including those of subunits, and a list of environmental assessments and environmental impact statements that are in development and complete. As appropriate, agencies also should include:

(1) Agency planning and other documents that guide agency management and provide for public involvement in agency planning processes;

(2) Environmental documents;

(3) Agency policy documents, orders, terminology, and explanatory materials regarding agency decision-making processes;

(4) Agency planning program information, plans, and planning tools; and

(5) A database searchable by geographic information, document status, document type, and project type.

(b) Agencies shall provide for efficient and effective interagency coordination of their environmental program websites and other information technology tools, such as use of shared databases or application programming interfaces, in their implementation of NEPA and related authorities.

PART 1508—DEFINITIONS

§ 1508.1 Definitions.

The following definitions apply to the regulations in this subchapter. Federal agencies shall use these terms uniformly throughout the Federal Government.

(a) *Act* or *NEPA* means the National Environmental Policy Act, as amended (42 U.S.C. 4321, *et seq.*).

(b) *Affecting* means will or may have an effect on.

(c) *Authorization* means any license, permit, approval, finding, determination, or other administrative decision issued by an agency that is required or authorized under Federal law in order to implement a proposed action.

(d) *Categorical exclusion* means a category of actions that an agency has determined, in its agency NEPA procedures (§ 1507.3 of this subchapter) or pursuant to § 1501.4(c) of this subchapter, normally does not have a significant effect on the human environment.

(e) *Cooperating agency* means any Federal, State, Tribal, or local agency with jurisdiction by law or special expertise with respect to any environmental impact involved in a proposal that has been designated by the lead agency.

(f) *Council* means the Council on Environmental Quality established by title II of the Act.

(g) *Effects* or *impacts* means changes to the human environment from the proposed action or alternatives that are reasonably foreseeable and include the following:

(1) Direct effects, which are caused by the action and occur at the same time and place.

(2) Indirect effects, which are caused by the action and are later in time or farther removed in distance, but are still reasonably foreseeable. Indirect effects may include growth-inducing effects and other effects related to induced changes in the pattern of land use, population density or growth rate, and related effects on air and water and other natural systems, including ecosystems.

(3) Cumulative effects, which are effects on the environment that result from the incremental effects of the action when added to the effects of other past, present, and reasonably foreseeable actions regardless of what agency (Federal or non-Federal) or person undertakes such other actions. Cumulative effects can result from actions with individually minor but collectively significant effects taking place over a period of time.

(4) Effects include ecological (such as the effects on natural resources and on the components, structures, and functioning of affected ecosystems), aesthetic, historic, cultural, economic, social, or health, such as disproportionate and adverse effects on communities with environmental justice concerns, whether direct, indirect, or cumulative. Effects also include climate change-related effects, including the contribution of a proposed action and its alternatives to climate change, and the reasonably foreseeable effects of climate change on the proposed action and its alternatives. Effects may also include those resulting from actions which may have both beneficial and detrimental effects, even if on balance the agency believes that the effects will be beneficial.

(h) *Environmental assessment* means a concise public document, for which a Federal agency is responsible, for an action that is not likely to have a significant effect or for which the significance of the effects is unknown (§ 1501.5 of this subchapter), that is used to support an agency's determination of whether to prepare an environmental impact statement (part 1502 of this subchapter) or a finding of no significant impact (§ 1501.6 of this subchapter).

(i) *Environmental document* means an environmental assessment, environmental impact statement, documented categorical exclusion determination, finding of no significant impact, record of decision, or notice of intent.

(j) *Environmental impact statement* means a detailed written statement that is required by section 102(2)(C) of NEPA.

(k) *Environmental justice* means the just treatment and meaningful involvement of all people, regardless of income, race, color, national origin, Tribal affiliation, or disability, in agency decision making and other Federal activities that affect human health and the environment so that people:

(1) Are fully protected from disproportionate and adverse human health and environmental effects (including risks) and hazards, including those related to climate change, the cumulative impacts of environmental and other burdens, and the legacy of racism or other structural or systemic barriers; and

(2) Have equitable access to a healthy, sustainable, and resilient environment

in which to live, play, work, learn, grow, worship, and engage in cultural and subsistence practices.

(*l*) *Environmentally preferable alternative* means the alternative or alternatives that will best promote the national environmental policy as expressed in section 101 of NEPA.

(m) *Extraordinary circumstances* are factors or circumstances that indicate a normally categorically excluded action may have a significant environmental effect. Examples of extraordinary circumstances include potential substantial effects on sensitive environmental resources, potential disproportionate and adverse effects on communities with environmental justice concerns, potential substantial effects associated with climate change, and potential adverse effects on historic properties or cultural resources.

(n) *Federal agency* means all agencies of the Federal Government. It does not mean the Congress, the Judiciary, or the President, including the performance of staff functions for the President in his Executive Office. For the purposes of the regulations in this subchapter, Federal agency also includes States, units of general local government, and Tribal governments assuming NEPA responsibilities from a Federal agency pursuant to statute.

(o) *Finding of no significant impact* means a document by a Federal agency briefly presenting the agency's determination that and reasons why an action, not otherwise categorically excluded (§ 1501.4 of this subchapter), will not have a significant effect on the human environment and for which an environmental impact statement therefore will not be prepared.

(p) *Human environment* or *environment* means comprehensively the natural and physical environment and the relationship of present and future generations with that environment. (*See also* the definition of ''effects'' in paragraph (g) of this section.)

(q) *Joint lead agency* means a Federal, State, Tribal, or local agency designated pursuant to § 1501.7(c) that shares the responsibilities of the lead agency for preparing the environmental impact statement or environmental assessment.

(r) *Jurisdiction by law* means agency authority to approve, veto, or finance all or part of the proposal.

(s) *Lead agency* means the Federal agency that proposes the agency action or is designated pursuant to § 1501.7(c) for preparing or having primary responsibility for preparing the environmental impact statement or environmental assessment.

(t) *Legislation* means a bill or legislative proposal to Congress developed by a Federal agency, but does not include requests for appropriations or legislation recommended by the President.

(u) *Major Federal action* or *action* means an action that the agency carrying out such action determines is subject to substantial Federal control and responsibility.

(1) Major Federal actions generally include:

(i) Granting authorizations, including permits, licenses, rights-of-way, or other authorizations.

(ii) Adoption of official policy, such as rules, regulations, and interpretations adopted under the Administrative Procedure Act, 5 U.S.C. 551 *et seq.,* or other statutes; implementation of treaties and international conventions or agreements, including those implemented pursuant to statute or regulation; formal documents establishing an agency's policies that will result in or substantially alter agency programs.

(iii) Adoption of formal plans, such as official documents prepared or approved by Federal agencies, which prescribe alternative uses of Federal resources, upon which future agency actions will be based.

(iv) Adoption of programs, such as a group of concerted actions to implement a specific policy or plan; systematic and related agency decisions allocating agency resources to implement a specific statutory program or executive directive.

(v) Carrying out specific projects, such as construction or management activities.

(vi) Providing financial assistance, including through grants, cooperative agreements, loans, loan guarantees, or other forms of financial assistance, where the agency has the authority to deny in whole or in part the assistance due environmental effects, impose conditions on the receipt of the financial assistance to address environmental effects, or otherwise has sufficient control and responsibility over the subsequent use of the financial assistance or the effects of the activity for which the agency is providing the financial assistance.

(2) Major Federal actions do not include the following:

(i) Non-Federal actions:

(A) With no or minimal Federal funding; or

(B) With no or minimal Federal involvement where the Federal agency cannot control the outcome of the project;

(ii) Funding assistance solely in the form of general revenue sharing funds that do not provide Federal agency compliance or enforcement responsibility over the subsequent use of such funds;

(iii) Loans, loan guarantees, or other forms of financial assistance where a Federal agency does not exercise sufficient control and responsibility over the subsequent use of such financial assistance or the effects of the action;

(iv) Business loan guarantees provided by the Small Business Administration pursuant to section 7(a) or (b) and of the Small Business Act (15 U.S.C. 636(a) and (b)), or title V of the Small Business Investment Act of 1958 (15 U.S.C. 695 through 697g);

(v) Judicial or administrative civil or criminal enforcement actions;

(vi) Extraterritorial activities or decisions, which means agency activities or decisions with effects located entirely outside of the jurisdiction of the United States;

(vii) Activities or decisions that are non-discretionary and made in accordance with the agency's statutory authority;

(viii) Activities or decisions that are not a final agency action within the meaning of such term under the Administrative Procedure Act; and

(ix) Activities or decisions for projects approved by a Tribal Nation that occur on or involve land held in trust or restricted status by the United States for the benefit of that Tribal Nation or by the Tribal Nation when such activities or decisions involve no Federal funding or other Federal involvement.

(v) *Matter* includes for purposes of part 1504 of this subchapter:

(1) With respect to the Environmental Protection Agency, any proposed legislation, project, action, or regulation as those terms are used in section 309(a) of the Clean Air Act (42 U.S.C. 7609).

(2) With respect to all other agencies, any proposed major Federal action to which section 102(2)(C) of NEPA applies.

(w) *Mitigation* means measures that avoid, minimize, or compensate for effects caused by a proposed action or alternatives as described in an environmental document or record of decision and that have a connection to those effects. Mitigation includes, in general order of priority:

(1) Avoiding the effect altogether by not taking a certain action or parts of an action.

(2) Minimizing effects by limiting the degree or magnitude of the action and its implementation.

(3) Rectifying the effect by repairing, rehabilitating, or restoring the affected environment.

(4) Reducing or eliminating the effect over time by preservation and maintenance operations during the life of the action.

(5) Compensating for the effect by replacing or providing substitute resources or environments.

(x) *NEPA process* means all measures necessary for compliance with the requirements of section 2 and title I of NEPA.

(y) *Notice of intent* means a public notice that an agency will prepare and consider an environmental impact statement or environmental assessment, as applicable.

(z) *Page* means 500 words and does not include citations, explanatory maps, diagrams, graphs, tables, and other means of graphically displaying quantitative or geospatial information.

(aa) *Participating agency* means a Federal, State, Tribal, or local agency participating in an environmental review or authorization of an action.

(bb) *Participating Federal agency* means a Federal agency participating in an environmental review or authorization of an action.

(cc) *Programmatic environmental document* means an environmental impact statement or environmental assessment analyzing all or some of the environmental effects of a policy, program, plan, or group of related actions.

(dd) *Proposal* means a proposed action at a stage when an agency has a goal, is actively preparing to make a decision on one or more alternative means of accomplishing that goal, and can meaningfully evaluate its effects. A proposal may exist in fact as well as by agency declaration that one exists.

(ee) *Publish* and *publication* mean methods found by the agency to efficiently and effectively make environmental documents and information available for review by interested persons, including electronic publication, and adopted by agency NEPA procedures pursuant to § 1507.3 of this subchapter.

(ff) *Reasonable alternatives* means a reasonable range of alternatives that are technically and economically feasible, and meet the purpose and need for the proposed action.

(gg) *Reasonably foreseeable* means sufficiently likely to occur such that a person of ordinary prudence would take it into account in reaching a decision.

(hh) *Referring agency* means the Federal agency that has referred any matter to the Council after a determination that the matter is unsatisfactory from the standpoint of public health or welfare or environmental quality.

(ii) *Scope* consists of the range and breadth of actions, alternatives, and effects to be considered in an environmental impact statement or environmental assessment.

(jj) *Senior agency official* means an official of assistant secretary rank or higher (or equivalent) that is designated for overall agency NEPA compliance, including resolving implementation issues.

(kk) *Significant effects* means adverse effects that an agency has identified as significant based on the criteria in § 1501.3(d) of this subchapter.

(*ll*) *Special expertise* means statutory responsibility, agency mission, or related program experience.

(mm) *Tiering* refers to the process described in § 1501.11 of this subchapter.

§ 1508.2 [Reserved]

[FR Doc. 2023–15405 Filed 7–28–23; 8:45 am]

BILLING CODE 3325–F3–P

FEDERAL REGISTER

Vol. 88 Monday,

No. 145 July 31, 2023

Part IV

The President

Proclamation 10604—National Korean War Veterans Armistice Day, 2023

Federal Register
Vol. 88, No. 145
Monday, July 31, 2023

Presidential Documents

Title 3—

The President

Proclamation 10604 of July 26, 2023

National Korean War Veterans Armistice Day, 2023

By the President of the United States of America

A Proclamation

This year marks the 70th anniversary of the Alliance between the United States and the Republic of Korea—an unbreakable bond forged by American and Korean service members who fought side-by-side from 1950 to 1953. These patriots braved dangers and deprivations, facing down war and death in defense of democracy. Today, we remember their service. Together, we honor their sacrifice—including more than 36,000 Americans and more than 7,000 Korean Augmentation to the United States Army soldiers who laid down their lives for a world of greater liberty and freedom.

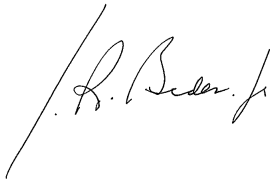
During President Yoon's recent trip to the United States, we visited the Korean War Veterans Memorial—laying wreaths in honor of the brave Korean and American women and men who served and sacrificed. It was a solemn reminder that our Alliance was not born out of shared borders but shared beliefs—including democracy, security, and freedom. Today, those beliefs are upheld by the thousands of Korean and American troops who continue to stand together on the Korean Peninsula. And they remain the source of our shared strength—keeping the Alliance between the Republic of Korea and the United States the linchpin of peace, stability, and prosperity in the Indo-Pacific region and, increasingly, around the world.

Today, we also pause to remember the thousands of United States troops who went missing in action during the Korean War. That includes Army Corporal Luther H. Story, who was awarded the Medal of Honor for his extraordinary heroism during a battle on the Pusan Perimeter in 1950. Our Nation was able to bring Corporal Story home this year when his remains were finally identified and returned to his family. And we will never stop working to bring home every one of our missing heroes.

Today—70 years after the armistice was signed by representatives of the United States as head of the United Nations Command, the People's Republic of China, and North Korea—let us honor the Korean War Veterans who fought to defend the security and stability we enjoy today. Let us renew our commitment to the democratic values for which they served and sacrificed. And together, let us continue to ensure that our Alliance with the Republic of Korea continues to contribute to global peace and prosperity.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim July 27, 2023, as National Korean War Veterans Armistice Day. On this day, I encourage all Americans to reflect on the strength, sacrifices, and sense of duty of our Korean War Veterans and bestow upon them the high honor they deserve. I call upon all Americans to observe this day with appropriate ceremonies and activities that honor and give thanks to our distinguished Korean War Veterans.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of July, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-eighth.



[FR Doc. 2023–16400
Filed 7–28–23; 11:15 am]
Billing code 3395–F3–P

Reader Aids

Federal Register

Vol. 88, No. 145

Monday, July 31, 2023

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations

General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**

Presidential Documents

Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**

Other Services

Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6050**

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, JULY

42587–42868 3
42869–43048 5
43049–43246 6
43247–43424 7
43425–44030 10
44031–44190 11
44191–44670 12
44671–45054 13
45055–45328 14
45329–45806 17
45807–46042 18
46043–46672 19
46673–46950 20
46951–47350 21
47351–47740 24
47741–48028 25
48029–48350 26
48351–48704 27
48705–49266 28
49267–49992 31

CFR PARTS AFFECTED DURING JULY

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Proclamations:
10599 46043
10600 46045
10601 48029
10602 48705
10603 48715
10604 49991
Executive Orders:
14102 45807
Administrative Orders:
Memorandums:
Memorandum of Jun. 27, 2023 43049
Memorandum of Jun. 30, 2023 43247
Memorandum of Jul. 7, 2023 44665
Memorandum of Jul. 7, 2023 44671
Notices:
Notice of Jul. 11, 2023 44669
Notice of Jul. 12, 2023 45327
Notice of Jul. 19, 2023 46951
Notice of Jul. 21, 2023 ..... 48025, 48027
Presidential Permits:
Permit of Jul. 6, 2023 44661

5 CFR

894 47741
2429 ..... 43425, 44191
Proposed Rules:
302 47059
332 47059
337 47059
843 45100
10300 45822

6 CFR

37 44191

7 CFR

800 45055
810 45055
3550 45809
3555 48031
3565 46047
Proposed Rules:
1000 47396
1005 46016
1006 46016
1007 46016
1206 49356
1222 48141

8 CFR

217 43051
274a 47749, 47990

9 CFR

Proposed Rules:
11 47068

10 CFR

50 ..... 44193, 47754
51 47755
52 ..... 44193, 47754, 47755
72 ..... 42587, 49267
73 48717
100 47755
429 48351
430 ..... 48035, 48351
1709 44031
Proposed Rules:
35 ..... 42654, 45824
72 49357
429 49058
430 49058

12 CFR

204 45057
701 48055
Proposed Rules:
34 47071
Ch. II 47071
323 47071
722 47071
Ch. X 47071
1227 47077

13 CFR

107 45982
121 ..... 45982, 46048
124 46048
127 46048
128 42592
134 42592
Proposed Rules:
115 48739
121 48739

14 CFR

21 46055
25 ..... 44032, 46953, 46955, 46956
39 ..... 42593, 42598, 42600, 42602, 42604, 42606, 42609, 42611, 43052, 43055, 43251, 43253, 43426, 44033, 44035, 44037, 44040, 44042, 44194, 44200, 44205, 46057, 46060, 46063, 46066, 46068, 46673, 46677, 46679, 47351, 47355, 47756, 48067, 48718, 49275, 49277, 49280, 49284
71 ..... 42614, 42869, 43429, 43430, 43431, 43432, 43433, 44673, 44674, 45058, 45329, 45810, 45811, 45812, 46681,

46682, 46683, 46685, 46687, 47358, 47359, 47361, 47362, 47363, 47365, 47366, 47367, 47369, 47757, 47759, 47760, 47762, 48070, 48358, 48359, 48361, 48362
73....48364
91....47765, 48072
95....45330
97....43058, 43059, 45060, 45061, 48720, 48722
110....48072
119....48072
121....48072
125....48072
136....48072
1204....42870, 44675
Proposed Rules:
1....47650
21....47650, 48142
22....47650
25....48142
36....47650
39....42884, 42886, 43477, 43479, 44065, 44068, 44075, 44226, 44228, 44232, 44235, 44740, 45102, 45106, 45109, 45112, 45115, 45118, 45121, 46112, 46115, 46118, 46697, 46699, 46702, 47084, 47086, 47090, 47092, 47399, 47402, 47404, 47827, 48393, 48760, 48764, 48767, 49361
43....47650
45....47650
61....44744, 47650
65....47650
71....42659, 42889, 43258, 44744, 45373, 45825, 46121, 48396
91....44744, 47650
119....47650

15 CFR
713....42615
744....46071
998....48723
2004....47772

16 CFR
0....42872, 45063
1....42872, 45063
2....42872, 45063
3....42872, 45063
4....42872, 45063
255....48092
1270....46958
Proposed Rules:
308....48771
312....46705
465....49364
1420....48398

17 CFR
39....44675
232....45814
Proposed Rules:
1....45826
23....45826
39....48968
190....48968
240....45836

20 CFR
Proposed Rules:
603....47829

21 CFR
Ch. I....45063
1306....46983, 48365
1308....46073, 48112
Proposed Rules:
573....48406

22 CFR
41....45068
42....45068
Proposed Rules:
50....48143
51....48143
71....48143

24 CFR
Proposed Rules:
5....45863
202....45863
203....49392

25 CFR
Proposed Rules:
226....43482

26 CFR
1....44210
31....48118
602....44210
Proposed Rules:
1....44596
54....44596
301....49397

27 CFR
9....42878

29 CFR
405....49230
1904....47254
4022....44045
4044....44045
4062....44045
Proposed Rules:
1926....46706
2590....44596

30 CFR
1202....47003
1206....47003
Proposed Rules:
56....44852, 48146
57....44852, 48146
60....44852, 48146
70....44852, 48146
71....44852, 48146
72....44852, 48146
75....44852, 48146
90....44852, 48146

31 CFR
525....45816
526....44052
542....45816
560....45816, 46688
591....45816
594....45816
601....43062

32 CFR
1700....48725

33 CFR
100....43063, 44216, 44694, 44698, 46073, 48125
117....49287
165....42619, 44698, 46700, 45338, 45339, 45818, 46075, 46689, 47020, 47022, 47772, 48731, 48732, 48734, 49288, 49290, 49292
Proposed Rules:
110....47837
165....45123, 47407

34 CFR
Ch. III....45340, 48129
Ch. VI....47370
600....43064
668....43064
674....43064
682....43064, 43820
685....43064, 43820
Proposed Rules:
Ch. VI....43069

37 CFR
1....45078
11....45078
222....48380, 49294
224....49294
225....49294
233....49294
234....49294
235....48380, 49294
Proposed Rules:
201....42891

38 CFR
21....45818
38....44219
Proposed Rules:
36....46720
80....42891

39 CFR
233....47024

40 CFR
52....42621, 42640, 43434, 43440, 44702, 44707, 46691, 47026, 47375, 47377, 47380, 48381, 49295
70....47029
71....47029
80....44468
81....47380
83....44710
84....44220, 46836
97....49295
180....43442, 46077, 47773, 47778, 48383
372....45089
704....47782
1090....44468
Proposed Rules:
52....42900, 43483, 44237, 44747, 45276, 45373, 46723, 47095, 47409, 47413, 47414, 48147, 48150, 48152, 48406, 48772, 49398
62....43259, 46123
63....47415, 49402
70....45373
81....48772
180....48179
720....46125
721....46125, 46726
723....46125
725....46125
751....49180
1500....49924
1501....49924
1502....49924
1503....49924
1504....49924
1505....49924
1506....49924
1507....49924
1508....49924

42 CFR
414....49309
1003....42820
1005....42820
Proposed Rules:
71....43978
136....45867
400–699 (Ch. IV)....45872
405....49552
409....43654
410....43654, 49552
414....43654
416....49552
419....44078, 45126, 49552
424....43654, 49552
484....43654
485....49552
488....43654, 49552
489....43654, 49552

43 CFR
Proposed Rules:
2....44748
3000....47562
3100....47562
3110....47562
3120....47562
3130....47562
3140....47562
3150....47562
3160....47562
3170....47562
3180....47562

45 CFR
5b....48736
2525....44721
2526....44721
2527....44721
2528....44721
2529....44721
2530....44721
Proposed Rules:
75....44750
98....45022, 48409
144....44596
146....44596
148....44596
180....49552
305....44760

47 CFR
0....43446, 44735
1....43460, 44735
2....43460, 43462
15....43460, 47384
25....43460, 43462
27....43460, 43462
64....43460
73....45347, 46086, 46087
74....43460, 45347
78....43460
80....44735
101....43460, 43462

Proposed Rules:
0 49423
1 ....43489, 43938
2 ....43502, 43938
9 43514
15 ....43502, 43938
25 ....43502, 43938
27 ....43502, 43938
64 43489
73 ....45126, 45376, 45377, 45378, 48784
74 ....43938, 45378
78 43938
101 ....43502, 43938

48 CFR

202 46903
212 ....46900, 46904
225 ....46900, 46904, 46906
234 46903
252 ....46900, 46904, 46906
532 43256
552 43256
1803 47807
1825 47807
3052 47054

49 CFR

391 43065
Proposed Rules:
171 43016
172 43016
173 43016
174 43016
175 43016
176 43016
177 43016
178 43016
179 43016
180 43016
245 42907
246 42907
385 47437
393 43174
396 43174
571 43174
596 43174
803 43070

50 CFR

10 49310
12 47808
17 ....42642, 46088, 46910, 49310
21 49310
300 ....47055, 48388
600 46692
622 ....42882, 45369, 46692
635 ....45369, 48136
648 ....44063, 48389
660 ....42652, 44737
679 ....44739, 45098, 45371, 46110, 47057, 48137
Proposed Rules:
17 ....42661, 46376, 47839, 47952, 48294, 48414
29 47442
223 46572
224 ....46572, 46727, 47453
226 ....46572, 47453
622 ....44244, 44764, 45384
660 48180
679 ....43072, 44096

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. This list is also available online at *https://www.archives.gov/federal-register/laws/current.html*.

The text of laws is not published in the **Federal Register** but may be ordered in ''slip law'' (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text is available at *https://www.govinfo.gov/app/collection/plaw*. Some laws may not yet be available.

H.R. 423/P.L. 118–11
Pala Band of Mission Indians Land Transfer Act of 2023
(July 28, 2023; 137 Stat. 60)

H.R. 3672/P.L. 118–12
To designate the clinic of the Department of Veterans Affairs in Indian River, Michigan, as the ''Pfc. Justin T. Paton Department of Veterans Affairs Clinic''. (July 28, 2023; 137 Stat. 62)

Last List July 28, 2023

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://portalguard.gsa.gov/__layouts/pg/register.aspx*.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.